

# EXHIBIT G

Nicolette S. Horbach, M.D.

1                   IN THE SUPERIOR COURT OF NEW JERSEY  
2                   LAW DIVISION - ATLANTIC COUNTY  
3                   DOCKET NO. ATL-L-6951-10  
4                   - - - - -  
5                   PAMELA WICKER and WILLIAM  
6                   WICKER,  
7                   Plaintiffs,                   Master Case No.  
8                   vs.                   L-6341-10-CT  
9                   ETHICON, INC., et al,  
10                   Defendants.

11                   Videotaped Deposition of  
12                   Nicolette S. Horbach, M.D.  
13                   Washington, D.C.  
14                   Friday, November 22, 2013  
15                   9:48 a.m.

16  
17  
18  
19  
20                   Reported by: Laurie Bangart, RPR, CRR

21  
22  
23                   Golkow Technologies, Inc.  
24                   877.370.3377 ph|917.591.5672 fax  
25                   www.golkow.com

Nicolette S. Horbach, M.D.

1 Videotaped Deposition of  
2 NICOLETTE S. HORBACH, M.D.

3

4 Held at the offices of:

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9

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18 Taken pursuant to notice, before  
19 Laurie Bangart, Registered Professional  
20 Reporter, Certified Realtime Reporter, and  
21 Notary public in and for the District of  
22 Columbia.

23

24

25

1 A P P E A R A N C E S

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16 ALSO PRESENT:

17 Ken Nuzzi, Videographer

18 Stephanie Gardner, Esq.

19

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21

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25

Nicolette S. Horbach, M.D.

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Nicolette S. Horbach, M.D.

1 P R O C E E D I N G S

2 THE VIDEOGRAPHER: We are now on

3 the record. My name is Ken Nuzzi. I'm a

4 videographer with Golkow Technologies.

5 Today's date is November 22, 2013. Our

6 starting time is 9:48 a.m. This deposition

7 is being held in Washington, D.C. in the

8 matter of Pamela Wicker and William Wicker

9 versus Ethicon, Inc.; Ethicon Women's

10 Health & Urology, a division of Ethicon,

11 Inc.; Gynecare; Johnson & Johnson; and John

12 Does 1 through 20.

13 Our deponent today -- this is being

14 heard in the Superior Court of New Jersey.

15 This docket number is ATL-L-6951. Our

16 witness today is Dr. Nicolette S. Horbach,

17 M.D.

18 Will counsel please identify

19 themselves and who they represent.

20 MR. SLATER: Adam Slater for the

21 plaintiffs.

22 MR. COMBS: Phil Combs on behalf of

23 the defendants.

24 THE VIDEOGRAPHER: Our court

25 reporter is Laurie Bangart, also with Golkow

1 Technologies. Ms. Bangart will now swear in  
2 our witness, please.

3 (Witness duly sworn.)

4 MR. COMBS: All right. Before,  
5 before we get started today, I'm just going  
6 to put a very brief objection on the record.

7 As far as I know, there isn't a  
8 notice for the deposition. That's fine.  
9 We've agreed to produce Dr. Horbach today,  
10 but I want to object to any video portion of  
11 that deposition being played at trial for the  
12 same reasons that Mr. Slater objected to the  
13 videotaping of Pam Wicker's deposition on  
14 Monday.

15 Again, I'm not going to throw a  
16 fit, say that the camera has got to be turned  
17 off, anything like that, but I want to  
18 reserve that right for that to be -- to  
19 object to that being played at trial.

20 MR. SLATER: Really? When did you  
21 make the decision that you were going to make  
22 that objection?

23 MR. COMBS: Today, Adam.

24 MR. SLATER: Really? Pam Wicker  
25 was deposed on Monday. It's now Friday.



1 MR. COMBS: Yeah.

2 MR. SLATER: You didn't think you  
3 should let me know in advance?

4 MR. COMBS: Listen --

5 MR. SLATER: I told Kelly Crawford  
6 unequivocally, and the protocol has been the  
7 plaintiffs are deposing every witness by  
8 video in this entire litigation. Every  
9 witness has been videotaped. The defense is  
10 on notice of that, that we are videotaping  
11 every single witness that we depose, and you  
12 walk in here and you make that objection now?  
13 I hope you won't raise it at trial. I'll ask  
14 for sanctions.

15 Now let's proceed.

16 MR. COMBS: You feel free to seek  
17 whatever relief you think is appropriate. I  
18 have made my objection, and the objection --

19 MR. SLATER: Okay. Why do you  
20 carry that on? You said what you needed to  
21 say. I responded. Now we're going to  
22 proceed --

23 MR. COMBS: No, I'm going to say --

24 MR. SLATER: -- back in New  
25 Jersey --

1 MR. COMBS: Hey.

2 MR. SLATER: -- we're going to  
3 proceed now.

4 MR. COMBS: You're not going to  
5 tell me not to talk. When I have an  
6 objection to make on the record, I'll make  
7 it.

8 Now --

9 MR. SLATER: Okay.

10 MR. COMBS: -- go ahead and proceed  
11 with your deposition.

12 MR. SLATER: I plan to. Welcome  
13 back to the United States from Germany.  
14 We're all happy to have you back. We're now  
15 going to proceed.

16 NICOLETTE S. HORBACH, M.D.,  
17 having been first duly sworn, testified  
18 upon her oath as follows:

19 EXAMINATION BY COUNSEL FOR PLAINTIFF

20 BY MR. SLATER:

21 Q Dr. Horbach, good morning.

22 A Good morning.

23 Q You understand you're under oath and  
24 that if you don't tell the truth in response to  
25 one of my questions, you can be criminally

1 prosecuted for perjury?

2 A I do.

3 MR. COMBS: Object to the form.

4 BY MR. SLATER:

5 Q Now, we've marked several exhibits. The  
6 first exhibit -- well, actually, before I go  
7 through that, let me just make one thing clear.

8 If I ask you a question you don't  
9 understand for some reason, tell me, please, and  
10 I'll rephrase it. Okay?

11 A Okay.

12 Q If I ask you a question that you're not  
13 sure you can answer truthfully and accurately and  
14 completely for any reason, tell me that before you  
15 answer the question. Okay?

16 A Okay.

17 Q If counsel objects, let him place his  
18 objection on the record, but if there's any  
19 discussion by counsel of any substance, he'll have  
20 to ask you to leave the room. He's not allowed to  
21 signal to you what he wants you to say or how to  
22 answer a question with an objection.

23 Do you understand that?

24 A Okay.

25

1 (Exhibit 1 was marked for  
2 identification.)

3 BY MR. SLATER:

4 Q We've marked as Exhibit 1 a document  
5 entitled "Curriculum Vitae," for you.

6 Is that your current CV?

7 A It's the most current printed. There's  
8 one change on the CV that's additional that is not  
9 on there.

10 Q What is that?

11 A That I am now a board-certified  
12 subspecialist in female pelvic medicine and  
13 reconstructive surgery.

14 (Exhibit 2 was marked for  
15 identification.)

16 (Discussion was held off the  
17 record.)

18 BY MR. SLATER:

19 Q Let's go to Exhibit 2. Please tell me  
20 what Exhibit 2 is.

21 A Exhibit 2 represents an expert report  
22 that I compiled regarding prolapse, per se, as  
23 well as Prolift in particular.

24 Q My understanding, this is your general  
25 report in this case.

1 Is that correct?

2 A Yes.

3 (Exhibit 3 was marked for  
4 identification.)

5 BY MR. SLATER:

6 Q Now can we look at Exhibit 3, please.  
7 What is Exhibit 3?

8 A Exhibit 3 is the report of my  
9 independent medical examination of Pamela Wicker  
10 and my opinions regarding that.

11 Q It also includes your -- what records  
12 you reviewed and what your opinions were based on  
13 the records you found to be significant to you?

14 A Yes. It's based on my discussions with  
15 Pamela regarding historical information she  
16 provided, as well as records, medical records that  
17 I used in asking those questions of Ms. Wicker.

18 (Exhibits 4 and 5 were marked for  
19 identification.)

20 BY MR. SLATER:

21 Q Let's look at Exhibit 4.

22 A I don't know which one is 4.

23 Yes. I'm sorry. Okay. Number 4.

24 Q Okay.

25 It's my understanding that Exhibit 4 is

1 the materials you had reviewed at the time that  
2 you authored the reports that we marked as  
3 Exhibits 2 and 3.

4 Is that correct?

5 A This is the material that I was  
6 provided. Not all of the material has been  
7 specifically reviewed by me or read by me in its  
8 entirety.

9 Q Okay. Let me rephrase my question then.  
10 Am I correct that Exhibit 4 is the list  
11 of materials that had been provided to you at the  
12 time that you were preparing your reports that we  
13 marked as Exhibits 2 and 3?

14 A Yes, although I would have to  
15 double-check whether anything was added subsequent  
16 to the time of my report. There is a supplemental  
17 list that I think is also included in this whole  
18 thing. Oh, that's number 5. Sorry.

19 So I believe that these are records that  
20 were available to me at the time that I was  
21 writing my report, yes.

22 Q Let me just be clear, because this --  
23 well, rephrase. Let me be clear.

24 This list of materials on Exhibit 4, did  
25 you have all those materials at the time that you

1 signed your reports, finalized your reports that  
2 we marked as Exhibits 2 and 3, your general and  
3 case-specific reports in this case?

4 A To the best of my knowledge, although I  
5 don't recall whether, in looking at the  
6 transcripts here, whether -- I don't think -- I'm  
7 not sure whether Dr. Raz's transcript was  
8 available to me at that time. Don't recall when  
9 he was deposed relative to when the report was  
10 written.

11 Q Am I correct that you did not read all  
12 the materials on this list?

13 A That is correct.

14 Q As you sit here now looking at the  
15 transcripts, would you be able to tell me what you  
16 read?

17 A Most likely, yes.

18 MR. COMBS: Well, wait, wait for  
19 the question.

20 MR. SLATER: I just asked the  
21 question.

22 MR. COMBS: Well, was the -- do you  
23 want her to do that? I wasn't sure, Adam, if  
24 the question was can you tell me --

25 MR. SLATER: Oh, I'm sorry. I

1           didn't know that I was -- I'm, I'm very  
2           sorry. Sometimes I -- I thought that that  
3           was clear. It obviously wasn't.

4                       MR. COMBS: I'm, I'm not  
5           complaining.

6 BY MR. SLATER:

7           Q     Doctor --

8                       MR. COMBS: If, if, if that's what  
9           you want her to do, she will do it. I'm, I'm  
10          not trying to interrupt you or complain about  
11          it.

12                      MR. SLATER: Can I just continue?

13                      MR. COMBS: Yeah.

14                      MR. SLATER: Okay. I'm going to  
15          continue.

16 BY MR. SLATER:

17          Q     Doctor, are you able to tell me, as you  
18          sit here now, which of those transcripts you  
19          actually read at the time you wrote your reports?

20          A     I believe I can provide you that  
21          information.

22                      Going down the list --

23          Q     Okay.

24          A     Do you want me just to go down the list?

25          Q     Yes, tell me what you read at the time



1     you had written the reports, which of the  
2     transcripts.

3             A     Amy Wicker, Katherine Wicker, David  
4     Weinstein, Dena Harris. I don't think this. Jane  
5     Wallace was for the supplemental report. Pamela  
6     Wicker times two, Polly Pinkham Herring, Richard  
7     Bercik, Robert Baldwin, Shlomo Raz, Ayoub, and  
8     bits and pieces of Lucente.

9             I don't recall -- although it may have  
10    been sent to me, I don't recall seeing William  
11    Wicker's transcript in the information that I had,  
12    so occasionally either I've misplaced it or it  
13    didn't get quite into the package.

14            Q     With regard to the balance of the  
15    transcripts that you didn't just list for me, did  
16    you read those subsequent to writing your reports,  
17    or no?

18            A     No.

19            Q     Let's go to the expert reports.

20                 Tell me which of those you read at the  
21    time you wrote your reports.

22            A     That would be harder for me to  
23    specifically say, because the report was written a  
24    year ago, but to the best of my recollection, I  
25    had read Margolis'. I read Ann Weber's.

1 I had read -- there -- I don't recall  
2 who the individual is, but she's had, she had an  
3 IME psychiatric evaluation from one of the  
4 physicians. Was that Dr. Payne perhaps? Whoever  
5 was the psychiatric IME, her report I also read.

6 I don't recall whether I had read  
7 Klinge's or Klinge, however you want to pronounce  
8 that. And I'm trying -- for some reason Susan  
9 Shott sounds like familiar, but I can't recall  
10 specifically whether I had read her report.

11 Q Do you know what Dr. Shott's opinions  
12 were in the case?

13 A I can't --

14 Q Or what her opinions are?

15 A No. I mean I can't recall well enough  
16 at this point a year past to be able to give that  
17 information.

18 Q So you don't know what, what Susan  
19 Shott's expert report addressed or what her  
20 testimony addressed; correct?

21 A I do not know at this moment, a year  
22 after I wrote the report.

23 Q Did you ever read any of the other  
24 expert reports after you wrote your reports?

25 A There were -- no, I did not. The ones

1 like pathology, et cetera, I did not.

2 Q Have you ever read Dr. Klinge's general  
3 expert report?

4 A The comment I made earlier was that I  
5 believe that I read it around the time of my  
6 expert report. I don't recall whether it was  
7 before or after, and I can't recall specifically  
8 for you right now, because again, it would have  
9 been a year ago, and I've read a lot of documents  
10 in the meantime.

11 Q Let's go to the section titled "Medical  
12 Records."

13 Did you read all of those medical  
14 records when you wrote your reports?

15 A I am quite sure that I read every single  
16 medical record that's on this list that was  
17 provided to me.

18 Q Let's go to the section titled  
19 "Literature."

20 Have you read every one of those  
21 articles that are listed?

22 A At some point either prior to the report  
23 or in the past as part of other educational  
24 endeavors.

25 Q If you found one of those articles

1 listed in the literature section to be of  
2 significance to you, did you cite to it or refer  
3 to it in your expert report?

4 A No, I did not.

5 Q Did you rely on all of these articles in  
6 writing your expert report, or were they simply  
7 put on the list just to be over inclusive?

8 MR. COMBS: Object to form.

9 THE WITNESS: I, I have read all of  
10 these in creating my expert report in  
11 addition to my, you know, clinical expertise.  
12 This is part and parcel of my clinical  
13 expertise.

14 BY MR. SLATER:

15 Q Are all of these articles listed in the  
16 literature section significant to you as a basis  
17 for the opinions you hold in this case?

18 A I would say yes in that either the  
19 article may substantiate my opinion, the article  
20 may be contra to my opinion, although I may  
21 disagree with parts of the article, but these were  
22 all part of what I have read and reviewed prior to  
23 the time of writing my general report.

24 So they -- I can't tell you, you know --  
25 I'll just say prior to writing the report, these

1 have all been reviewed, so they all are a basis  
2 for my opinion.

3 Q Let's look, if you go to the Ks, because  
4 I guess it's in alphabetical order. About midway  
5 down the page, there's four articles by Klinge --

6 A Yes.

7 Q -- the, the name of the author you  
8 listed.

9 Let's go to the first one. It's titled  
10 "Foreign Body Reaction to Meshes Used for the  
11 Repair of Abdominal Wall Hernias," published in  
12 1999 in the OP Journal of Surgery.

13 Do you see that?

14 A Yes.

15 Q Okay.

16 What is significant about that article,  
17 in your opinion?

18 A It discusses prior experiences with the  
19 body's reaction to mesh placed in other locations.

20 Q Was there anything in particular in the  
21 article that was of significance to you?

22 A The -- I mean it's the entire  
23 information and how the body reacts and  
24 discussions regarding some of the microscopic  
25 evaluation of how the body reacts to meshes in the

1 abdominal wall, which may, may or may not be how  
2 the body reacts to meshes in the vaginal area.  
3 It's a background of --

4 Q Does the body react -- I'm sorry.

5 Does the body react the same way the  
6 meshes -- rephrase.

7 Is the body's reaction to meshes in the  
8 abdominal wall the same as the body reactions to  
9 meshes in the female pelvis?

10 A Not necessarily.

11 Q What do you mean by that?

12 A It may or may not. There are different  
13 parts of the body, and sometimes even in the  
14 abdominal wall, use of meshes for hernias, there's  
15 going to be differences in how a body will react  
16 from one patient to another, similar to what may  
17 happen in the vagina.

18 Q As a general proposition, what are the  
19 differences in the body's reaction to the mesh  
20 material used in the Prolift when it's in the  
21 abdominal wall as opposed to when it's in the  
22 female pelvis?

23 Can you give me some general differences  
24 about how the body will react to that mesh  
25 material? Do you have an opinion on that?

1           A     I can give you information about how the  
2     body can react to it. I don't know that I can  
3     predict that it will react in that way.

4           Q     Well, I want to know if you have an  
5     opinion to a reasonable degree of medical  
6     probability where you can say the body will react  
7     differently to Gynemesh PS mesh material when it's  
8     in the abdominal wall versus when it's in the  
9     female pelvis, and tell me what those differences  
10    are.

11          A     Again, you're asking me to say a will as  
12    a definitive statement of future, and I can't. I  
13    will tell you what the body -- how the body may  
14    react to the mesh in the vagina versus in the  
15    abdomen and the differences that you may see in  
16    those patients, but I can't say that it's a will  
17    as an absolute.

18          Q     Well, reasonable degree of medical  
19    probability means more likely than not.

20                Can you give me an opinion to a  
21    reasonable degree of medical probability on that  
22    question?

23          A     About how it may react in the vagina?

24          Q     Is there an understanding that the body  
25    will react differently to Gynemesh PS mesh when

1 it's placed in the abdominal wall versus when it's  
2 placed in the female pelvis? Is there a generally  
3 accepted understanding that it will react  
4 differently in any way in those two different  
5 parts of the body?

6 MR. COMBS: Object to form.

7 THE WITNESS: There's some  
8 information that there may be a different  
9 reaction in those different parts of the  
10 body, yes.

11 BY MR. SLATER:

12 Q And what is that?

13 A Well, part of the difficulty for the  
14 vaginal area as opposed to the abdominal wall is  
15 the nature of the environment, whether you're  
16 dealing with a clean operative field versus  
17 technically a clean contaminated field, although  
18 that raises some of the controversial issues of  
19 whether or not you can see infections or chronic  
20 infections in the vagina relative to mesh, which I  
21 don't think has been totally resolved one way or  
22 the other.

23 You also have differences relative to  
24 the depth of tissue layers. In the abdominal  
25 wall, the mesh has the advantage of having blood



1 flow that can come from either above or below, so  
2 the abdominal skin isn't necessarily -- or the  
3 abdominal subcutaneous tissue isn't necessarily  
4 totally dependent on blood flow from below and  
5 through the mesh to be able to survive, whereas in  
6 the vaginal area, the blood flow has to be able to  
7 either come partially through the mesh or it has  
8 to come laterally from the mesh to be able to  
9 continue to provide blood flow to the vaginal  
10 wall.

11 The issue about the degree of potential  
12 scarring and contracture that occurs in the two  
13 locations, there have been, you know, studies that  
14 have said significant contracture in the abdominal  
15 area, some studies saying less. Some studies say  
16 significant contraction in the vaginal area. Some  
17 studies say more.

18 So the difficulty is there's not an  
19 absolute agreement on how everyone will -- how  
20 each woman will react to the mesh placed in the  
21 vaginal area.

22 Q Any other differences?

23 A I think that probably -- I'm trying to  
24 remember the issues relative to the sort of  
25 scarring and microscopic sort of scar plating, et

1 cetera. I -- it's been a year or so since I had  
2 specifically read that article, so I would have to  
3 pull it again to be able to specifically address  
4 that with you.

5 Would you like me to do that?

6 Q Well, I wasn't, I wasn't just asking  
7 about the article. I'm asking you about, in  
8 general, your understanding of the differences in  
9 how the body will react to the mesh, whether in  
10 the abdomen or the female pelvis.

11 You understood that; right?

12 A Okay. That was not clear to me in the  
13 question. I thought you were saying -- referring  
14 specifically to this article of how it reacts in  
15 the abdomen versus other information about how it  
16 reacts in the vagina.

17 Q Well, the article that I cited to you  
18 doesn't talk about the reaction of the mesh in the  
19 female pelvis or vagina at all.

20 It's not even addressed in that article;  
21 correct?

22 A Correct.

23 Q So what you were telling me about was  
24 your general understanding of the different  
25 reactions of the human body to the mesh, whether

1 it's in the abdomen or the female pelvis; correct?

2 A Yes, based on some of the information in  
3 this article that was specifically cited versus  
4 how it reacts in the abdominal area. My  
5 statements about the vaginal area reactions were  
6 based on other articles and/or experience.

7 Q Okay.

8 Well, based on all of your knowledge as  
9 you sit here right now, are there any other  
10 differences in how the body will react to Gynemesh  
11 PS mesh, whether it's in the abdomen versus in the  
12 female pelvis?

13 A Well, yes. There, there certainly is  
14 going to be a, a risk in the female pelvis or when  
15 it's placed in the vagina, of -- erosions of the  
16 mesh is going to be higher than what you would  
17 typically see in the abdominal wall.

18 That really reflects the information  
19 that I had just discussed relative to blood flow,  
20 that, you know, if you don't have blood flow to  
21 those -- to the tissue in your optimal way, then  
22 you may have that tissue die, and you may  
23 experience a subsequent erosion or extrusion of  
24 the material.

25 There can be neurologic irritation or

1 neurologic symptoms post placement of a mesh  
2 inside of the abdominal wall for hernia. It's  
3 difficult to determine whether or not that is  
4 related to the mesh itself creating an issue or if  
5 it's specifically more related to the surgery, and  
6 so the similar situation would, would be present  
7 in the vaginal area, that a mesh in and of itself  
8 is not going to create a neuropathy or an injury  
9 or a problem with the primary nerves to the  
10 pelvis.

11 Q Do you have an understanding of what  
12 Ethicon Medical Affairs believes with regard to  
13 whether or not when a woman has contraction of  
14 mesh in her pelvis, and she complains of pain, as  
15 to whether or not nerves are being involved in  
16 that process?

17 MR. COMBS: Object to form.

18 THE WITNESS: I didn't know -- I do  
19 not know what Ethicon Medical believes.

20 BY MR. SLATER:

21 Q You agree with me that if there is  
22 contracting mesh in the female pelvis and it's --  
23 and the woman is complaining of pain, that the  
24 pain is, is due to nerves being impacted by the  
25 contracting mesh; correct?

1 MR. COMBS: Object to form.

2 THE WITNESS: I disagree with that  
3 statement. Well, actually, I don't agree  
4 with that statement as an absolute causative  
5 situation.

6 BY MR. SLATER:

7 Q It's more likely than not that if a  
8 woman has a foreign body reaction and contraction  
9 of the mesh, that -- and that caused pain to the  
10 woman, it's more likely than not that nerves are  
11 involved in that process; correct?

12 A Well, the way you've asked the question,  
13 yes, nerves are involved, because nerves end up  
14 conducting the sensation of pain, but that the  
15 mesh is the causative situation in that in a  
16 particular patient, you know, that's not something  
17 that you can say to a complete degree of medical  
18 certainty, no.

19 Q I'm going to take a hypothetical.

20 A woman has Prolift mesh in her pelvis.  
21 There is a foreign body reaction to the mesh. It  
22 causes an inflammatory response, leading to the  
23 creation of fibrotic tissue. That fibrotic tissue  
24 interacts with the mesh and causes the mesh to be  
25 contracted down by the, by the fibrotic tissue.

1 The woman feels and experiences pain.

2 In that scenario, it's more likely than  
3 not that nerves are being impacted by this  
4 process, leading to the sensation of pain;  
5 correct?

6 MR. COMBS: Object to form.

7 THE WITNESS: I agree that nerves  
8 are being impacted, causing pain, but I won't  
9 agree to within a medical degree of certainty  
10 that the mesh is the underlying reason that  
11 the patient is experiencing the nerves  
12 sensation of pain.

13 BY MR. SLATER:

14 Q In my hypothetical, why do you say that?

15 A Because you have to postulate, you know,  
16 what you're talking about. Well, first of all,  
17 you have to postulate that the patient's ability  
18 to sense pain and recognize pain is appropriately  
19 mapped, essentially, in her brain, that then ends  
20 up being associated with the area that's involved,  
21 because there -- oftentimes the neurologic  
22 sensation, especially in the pelvis, and where the  
23 patient perceives their sensation of pain isn't  
24 necessarily related to a pathology in that  
25 specific location.

1 Q All right.

2 Well, in my hypothetical, what's the  
3 alternative likely cause of the pain other than  
4 nerves being impacted by this process I described  
5 in my hypothetical?

6 A I can't make that decision without  
7 having examined the patient to do a pain  
8 evaluation.

9 Q You would agree with me that my  
10 hypothetical, as I phrased it, that it would be  
11 reasonable if somebody were to say, well, that  
12 process is leading to the pain that the woman is  
13 experiencing?

14 That would be a reasonable diagnosis;  
15 correct?

16 MR. COMBS: Object to form.

17 THE WITNESS: I think it's a  
18 possible diagnosis, but I don't think it's  
19 the only diagnosis that's present. You have  
20 to look for other causes of why the patient  
21 may experience pain.

22 BY MR. SLATER:

23 Q What would be the other potential  
24 alternative causes in my hypothetical?

25 A Well, it depends a little bit on where

1 the mesh is, which part of the body the mesh is  
2 placing that you're saying has the reaction, if  
3 you're saying it's anterior wall versus, you know,  
4 lateral wall versus posterior.

5 Q I don't understand what you're --  
6 honestly, with all due respect, I don't even  
7 understand what that means.

8 A That means you're telling me she had  
9 mesh placed and that she's having a reaction, so  
10 the question --

11 Q I said Prolift.

12 A Yeah.

13 Q I said Prolift.

14 A Fine. A Prolift placed.

15 The question is where in the vagina is  
16 the area that you're talking about that the  
17 patient is having discomfort and sensitivity.

18 Q Okay.

19 Let's say it's anterior Prolift, and  
20 she's complaining of the pain and the sensitivity  
21 in the anterior wall or anterior portion of her  
22 vagina and anterior part of the pelvis near the  
23 anterior wall.

24 A Okay.

25 So in that case, you're going to have to



1 rule out that there is any underlying urinary  
2 pathology going on, whether it's urethral or  
3 bladder. You also have to rule out any -- you  
4 know, depending on if the patient has gynecologic  
5 organs, you have to rule out the gynecologic  
6 organs, per se.

7 Alternatively, you also need to rule out  
8 aspects of the overall pelvis and the pelvic --  
9 the, the muscular situation, the ligaments that,  
10 that could also be contributing to the pain.

11 Probably -- I mean although it would be  
12 difficult for a patient to have a gastrointestinal  
13 issue that's going to refer specifically to  
14 pinpoint in the vagina anteriorly, that would be  
15 pretty unusual. I think it would have to be more  
16 from a bladder standpoint, but there are other  
17 reasons that a patient can experience pain.

18 Q There may be other reasons, but my  
19 scenario as refined by defining a Prolift anterior  
20 system and the complaints of pain in the anterior  
21 portion of the vagina, in that scenario, the  
22 likely cause of the pain would be the  
23 contracted -- the contraction of the mesh and this  
24 inflammatory reaction; correct?

25 MR. COMBS: Object to form.

1 THE WITNESS: I can't say that, no.

2 BY MR. SLATER:

3 Q Okay.

4 When a woman has scarring and  
5 contraction of a Prolift in her pelvis, that can  
6 lead to clinically significant pain for the woman;  
7 correct?

8 A I can, I can answer that question in  
9 such a way that if a patient experiences pain  
10 after having had a Prolift placed, there is a  
11 possibility that the Prolift is involved with the  
12 pain issue.

13 Q If a woman has a Prolift put in her  
14 body, and the mesh contracts and also the mesh  
15 erodes, leading to multiple operations, and the  
16 woman is complaining of pain and discomfort from  
17 the point the Prolift is in her body going forward  
18 through this contraction of the mesh and the  
19 erosions that are being treated, it's likely that  
20 the Prolift is certainly a cause, if not the only  
21 cause, since there may be other factors, but  
22 certainly it is a cause of that pain most likely;  
23 correct?

24 MR. COMBS: Object to form.

25 THE WITNESS: I think it depends on

1 the time period in which the -- you know,  
2 you're talking about the evaluation of the  
3 patient with pain.

4 If you're saying she's had multiple  
5 surgeries and she's had erosion and she's had  
6 her -- she's had mesh removed, then if you're  
7 palpating in an area of the vagina that does  
8 not have mesh, then at that particular time  
9 the mesh is not causing the patient's symptom  
10 of pain.

11 BY MR. SLATER:

12 Q Are you aware of the fact that a woman  
13 may have either contracted mesh or eroding mesh  
14 that contributed to an inflammatory reaction that  
15 led to scar tissue formation in that area, but the  
16 mesh can be removed, but the remaining scar tissue  
17 can continue to cause pain and discomfort for the  
18 woman?

19 You'd agree with that statement;  
20 correct?

21 A I think that that's an accurate  
22 statement that, yes, that you can still have pain  
23 from the scarring, yes.

24 Q Let's look now again at your materials  
25 reviewed. Let's go to the second Klinge article,

1 "Functional and Morphological Evaluation of a Low  
2 Weight Monofilament Polypropylene Mesh for Hernia  
3 Repair."

4 What was the significance of that  
5 article to you?

6 A Again, it goes into the issue of what  
7 the microscopic changes are in meshes relative to  
8 pore size. Different --

9 Q What's your understanding --

10 A Different pore sizes --

11 Q Sorry, sorry.

12 A Different pore sizes of mesh will  
13 typically induce a different reaction in a  
14 biologic system.

15 Q And what's your understanding as to the  
16 significance of a one millimeter pore size in all  
17 directions? Do you have an understanding of the  
18 significance to that figure?

19 MR. COMBS: Object to form.

20 THE WITNESS: Is it versus  
21 something else, or -- I mean it usually is --

22 BY MR. SLATER:

23 Q Does that have any meaning to -- I'll  
24 ask it differently.

25 If I say to you there is a significance

1 to whether or not the pores of a mesh used to  
2 treat pelvic organ prolapse maintain a one  
3 millimeter pore size in all directions under  
4 strain, once in the body, does that statement have  
5 any significance to you? Does that make sense to  
6 you?

7 A Yes.

8 Q You agree with that?

9 A Can you make the statement again so I  
10 can determine whether or not I agree with it.

11 Q Let's ask the court reporter to read it  
12 back to you, slowly.

13 (Whereupon, reporter reads  
14 requested material.)

15 MR. COMBS: Object to form.

16 THE WITNESS: Again, the statement  
17 "under strain," I'm not quite sure. You  
18 know, I understand that part of it, but I  
19 think that if the -- that maintaining optimal  
20 pore size would ideally have an impact on how  
21 the mesh may respond in a patient.

22 BY MR. SLATER:

23 Q And what you mean by that is if you've  
24 maintained an optimal, optimal pore size of one  
25 millimeter in all directions, that is understood

1 to reduce the risk of scar plating and bridging  
2 fibrosis and negative clinical impacts; correct?

3 MR. COMBS: Object to form.

4 THE WITNESS: In the -- I mean in  
5 the hypothetical and in certain situations,  
6 yes, but it may not make a difference in  
7 other situations. So I think that that's,  
8 that's a difficult statement to make as a  
9 global statement.

10 BY MR. SLATER:

11 Q Well, as a general statement in regard  
12 to the Prolift, you would agree that maintaining  
13 pore size of one millimeter in all directions when  
14 the mesh is actually in the body would reduce the  
15 risk of scar plating and bridging fibrosis and  
16 negative clinical impacts related to those --

17 A It could --

18 MR. COMBS: Object to form.

19 BY MR. SLATER:

20 Q -- phenomena; correct?

21 MR. COMBS: Object to form.

22 THE WITNESS: It could reduce the  
23 risk. I'm not saying -- I don't think you  
24 could say it would absolutely reduce the  
25 risk.

1 BY MR. SLATER:

2 Q Meaning it can still occur even if you  
3 maintain the one millimeter pore size, but if you  
4 maintain that pore size, there's less risk of it  
5 occurring?

6 Do I understand you?

7 MR. COMBS: Object to form.

8 THE WITNESS: I think in the  
9 hypothetical case I would probably agree with  
10 that. I mean the problem is in, in humans we  
11 can't really run those kind of experimental  
12 studies and make those types of comparisons.

13 BY MR. SLATER:

14 Q Are you aware of studies of explanted  
15 mesh that have been performed by Dr. Klinge and  
16 Dr. Klosterhoff, where they have actually measured  
17 the pore sizes --

18 A Yes.

19 Q -- upon explant from the human body?

20 A Yes.

21 Q And you're, and you're familiar with  
22 their theory that -- well, rephrase.

23 And you're -- are you familiar with  
24 their findings that when they found -- well,  
25 rephrase.

1                   And you're familiar with their findings  
2   that confirmed that it's very important to  
3   maintain at least a one millimeter pore size in  
4   actual use in the body to try to reduce the risk  
5   of scar plating, bridging fibrosis, resulting  
6   contraction and erosion; correct?

7                   MR. COMBS: Object to form.

8                   THE WITNESS: I don't think that  
9   they can make that conclusion based on  
10  removal of explants from symptomatic  
11  patients. You have to be able to compare  
12  that to explants removed from patients who  
13  may not be symptomatic or who may or may not  
14  have scar tissue, to be able to make a  
15  comparison how the body is going to respond  
16  if the pore sizes stay at one millimeter  
17  versus how the body is going to respond if  
18  they don't at, you know, less than a  
19  millimeter.

20                  You know, you can't run a  
21  controlled evaluation in the individual  
22  patient. You have -- would have to, to be  
23  able to also look at, you know, other  
24  patients who are either not symptomatic,  
25  don't have any scarring, don't have that so



1           that you can make a comparison.

2                       Otherwise you're just saying in  
3           this particular patient and in this  
4           particular situation, there is an association  
5           that this particular patient has scarring and  
6           a narrower pore size.

7                       But to be able to say, you know,  
8           that that won't happen or will happen  
9           depending upon what the mesh does pore size  
10          in a different patient, I don't think you can  
11          make that statement.

12   BY MR. SLATER:

13           Q       Based on the scientific literature that  
14   you've read, you would agree as a general  
15   proposition that for the Prolift, if it can  
16   maintain a one millimeter pore size in actual use  
17   in the body, that that would reduce the risk of  
18   bridging fibrosis, scar plating, contraction and  
19   erosion?

20                    As a general proposition, that is the  
21   understanding in the literature that you've  
22   reviewed; correct?

23                    MR. COMBS:   Object to form.

24                    THE WITNESS:   That is what is  
25   proposed in the literature by some

1 individuals. You know, whether they have,  
2 again, you know, sufficient information to  
3 make that assumption or make that conclusion  
4 I think is questionable.

5 BY MR. SLATER:

6 Q That's what the considered -- well,  
7 rephrase.

8 That is what the, the thought is in the  
9 literature you've reviewed now, at this point?

10 That's what the thinking is; correct?

11 MR. COMBS: Object to form.

12 THE WITNESS: That is what some  
13 people have thought in -- that have written  
14 their conclusions, but, you know, any of  
15 these different individuals can publish an  
16 article, publish their findings, and they can  
17 make a conclusion that doesn't necessarily  
18 mean that that conclusion is valid and can be  
19 extrapolated across the board.

20 BY MR. SLATER:

21 Q Do you, do you know whether or not  
22 Medical Affairs at Ethicon believes that what I  
23 just said to you is accurate?

24 A I do not know what Ethicon Medical  
25 Affairs believes.

1 Q Do you agree with me that Dr. Klinge and  
2 Professor Klosterhoff are probably the two most  
3 preeminent experts in the world with regard to  
4 this subject of pore size and what impact that can  
5 have clinically for a patient, in the world?

6 MR. COMBS: Object to form.

7 THE WITNESS: I think that they are  
8 individuals that are -- have done a  
9 tremendous amount of research and have a,  
10 have a strong knowledge base on it, but I  
11 don't know that they -- you know, if they're  
12 only evaluating meshes that are explanted  
13 from symptomatic individuals, you can't draw  
14 that conclusion that the findings that they  
15 see are, you know, absolutely a causative  
16 reason for why the patient -- why the  
17 scarring is there.

18 BY MR. SLATER:

19 Q Move to strike.

20 Would you agree with me that Dr. Klinge  
21 and Professor Klosterhoff are probably considered  
22 to be the two most preeminent scientists in the  
23 world with regard to the question of the  
24 significance of pore size in meshes used within  
25 the human body?

1 And limit it to that question.

2 Would you agree with that statement?

3 A I think they're one of the major  
4 authorities. I don't know if I would say the most  
5 authority.

6 Q Can you name anybody else?

7 A No.

8 Q Do you know whether or not Dr. Klinge  
9 and Professor Klosterhoff told Ethicon that they  
10 believed that the pores need to be at least one  
11 millimeter in all directions in actual use in the  
12 body to be safe?

13 A I don't know whether they told Ethicon  
14 that or not.

15 Q Let's go to the fourth Klinge article,  
16 "PVDF as a New Polymer for the Construction of  
17 Surgical Meshes."

18 Do you know what PVDF is?

19 A I did at one point. I'm trying to  
20 remember at this point now.

21 Q Are you pulling the article out?

22 A I'm looking to see if I have it, yes.

23 Q What PVDF is?

24 A I'm looking to see whether I have that  
25 article in my folder here.

1           Q     Doctor, Doctor, my question is: As you  
2     sit here now without looking at the article, do  
3     you know what PVDF is?

4           A     I can't say that right this minute, no.

5           Q     Okay.

6                     That was my question.

7           A     I had previously answered that.

8           Q     You listed articles here by Neilson,  
9     several articles regarding the TVT.

10                    Why were those listed?

11          A     Oh, I'm sorry.

12                    The -- some of the original information  
13     regarding how mesh responds in the body or in a  
14     tunnel of the body can be potentially looked at  
15     when you look at a TVT type procedure where  
16     similar strips or arms of material have been  
17     placed in the body.

18          Q     Do you know whether or not these  
19     articles by Neilson actually deal with the TVT  
20     that was marketed by Ethicon?

21                    MR. COMBS: Object to form.

22                    THE WITNESS: I can't recall that.

23     BY MR. SLATER:

24          Q     Do you feel that there can be  
25     significance to -- well, rephrase.

1                   Even though the TVT is a different  
2   device than the Prolift, do you feel that  
3   information as to how the TVT reacts with tissue  
4   can be significant to you with regard to how the  
5   Prolift will react in the body?

6           A     Yes. In my clinical experience, yes.

7           Q     Look at the cytotoxicity testing for the  
8   TVT?

9           A     Did I look at that?

10          Q     Yes.

11          A     No.

12          Q     Do you, do you know what cytotoxicity  
13   testing is?

14          A     I don't know the specific testing that  
15   would be done for it, but I'm basing this based on  
16   my clinical experience with dealing with these  
17   types of materials and meshes placed in the body  
18   under the epithelium and in the, in the tissues of  
19   the pelvis.

20          Q     Move to strike after, I think the answer  
21   was something to the effect of "I don't know what  
22   cytotoxicity testing is," and then there was --  
23   the second part of the answer is about the  
24   doctor's own experience. I'm moving to strike  
25   that second part of the answer.

1 Did anybody ever tell you that the  
2 cytotoxicity testing for the TVT showed that it  
3 had moderate to severe cytotoxicity, which was an  
4 indicator that there were the potential issues  
5 with biocompatibility of that mesh in the human  
6 body?

7 Were you ever aware of that?

8 MR. COMBS: Object to form.

9 THE WITNESS: No.

10 BY MR. SLATER:

11 Q Are you aware of what Ethicon told the  
12 FDA with regard to whether or not comparison of  
13 the Prolift to the TVT was appropriate in  
14 determining the safety and effectiveness for the  
15 Prolift?

16 A No, I don't know what Ethicon told the  
17 FDA regarding that.

18 Q You have a long list of articles here,  
19 and I certainly don't want to ask you about every  
20 single one of them.

21 If you were to be walking up to the  
22 witness stand right now, and you wanted to tell  
23 the jury what you thought were the ten most  
24 important articles to support your opinions on  
25 this literature list, which ones would you point

1 to?

2 A It would totally depend upon what  
3 questions I was asked regarding my opinions.

4 Q Obviously I don't want to be in a  
5 guessing game, so let me take a step back.

6 Your report does not specifically refer  
7 to the articles on this literature list; correct?

8 A It does not reference them specifically  
9 during the report, no.

10 Q So if I look at your report, that will  
11 not tell me which of those articles you believe to  
12 be most significant to you, because they're not  
13 identified?

14 A I'm not sure that question to be the,  
15 the reason -- or "because" I don't think is, is a  
16 valid comment. I have --

17 Q Let me tell you what I'm trying to get  
18 at. You gave me the answer. That's fine.

19 Here's what I'm asking you.

20 You are now on the witness stand in  
21 front of the jury in New Jersey, and you get asked  
22 the following question by counsel for  
23 Johnson & Johnson: "Doctor, you have a long list  
24 of literature here in the materials you reviewed.  
25 Can you tell me your top ten list of the most



1 important ten articles that support your opinions  
2 in this case?"

3 Can you point those out to me, please.

4 MR. COMBS: Object to the form.

5 THE WITNESS: I mean I can't -- I  
6 can potentially tell you articles that I  
7 think are important relative to my expert  
8 report, but since I am not, you know, able to  
9 know exactly what opinions are going to be  
10 asked of me at -- in the future on the stand  
11 by either counsel for defense or by counsel  
12 for the plaintiff, I can't sit there and say  
13 these are the ten most important articles.

14 BY MR. SLATER:

15 Q So you can't answer that, answer that  
16 question for me as you sit here now?

17 A Correct. I don't think that I would  
18 be -- it would be an accurate answer if I tried.

19 Q Let me ask you this.

20 Your reports, which we -- well, all  
21 right. Let me, let me just -- we'll come back to  
22 that.

23 In your list of materials reviewed,  
24 there's a section titled "Other."

25 Am I correct you have not read all of

1 those materials on that list?

2 A There are -- one that I see sort of  
3 right off, off the bat is that I have not reviewed  
4 or read the plaintiff's specific complaints or her  
5 I guess plaintiff's answers to uniform whatever,  
6 the first two things listed. I don't recall  
7 reading that.

8 Q Are you able to tell me which of these  
9 materials you actually reviewed and are relying on  
10 for your opinions?

11 A It will be all of the material that I  
12 don't tell -- sort of it's the opposite. I will  
13 tell you which ones I didn't do, because all the  
14 rest of it would be in there.

15 Q Okay.

16 A So the first two I had told you.

17 Q That's fine.

18 A I don't recall having read the memo to  
19 customer from Sean O'Brien.

20 Q So you're on the next page now?

21 A Yes.

22 On the final page there are two articles  
23 about the tissue reaction or biocompatibility.  
24 I'm quite sure that I read the first one on the  
25 tissue reaction in the rat. Don't recall at this

1 point whether or not I read the second one. I may  
2 have. I just don't recall now a year later.

3 Q The second one is the Ethicon  
4 biocompatibility risk --

5 A Correct.

6 Q -- assessment for the --

7 A Right.

8 Q -- Prolift?

9 A I may or may not have. Again, I'm  
10 trying to remember what I read a year ago.

11 Q As you sit here now, is that document of  
12 any significance to you?

13 A The, the biocompatibility risk document?  
14 Is that what you're asking?

15 Q Yes.

16 A Well, if I don't remember whether I read  
17 it or not, I'm not sure I can tell you whether it  
18 is of any significance to me.

19 Q Is the 91-day tissue reaction study with  
20 the rat of significance to you?

21 A Again, it depends on what you mean by  
22 significant. It is a -- it is one of the studies  
23 that was done to look at tissue reactivity in an  
24 animal model for a, you know, similar type of  
25 mesh, but -- and I know that there were some

1 different reactivity issues but that there was  
2 not, at least at this point, a specific -- the  
3 reaction was not as pronounced as -- I'll just,  
4 I'll just stop there. Sorry.

5 Q Anything about the 91-day rat study as  
6 cited right here, that as you sit here now you can  
7 say the result of that study is important in  
8 supporting my opinions for this reason? Can you  
9 tell me that?

10 A The rat study I guess I would say is  
11 important because it is an animal model evaluation  
12 to look for tissue reactivity from the  
13 polypropylene mesh that was done prior to the  
14 launch of Prolift.

15 Q And what, if anything, about the results  
16 is significant to you in supporting your opinions?

17 A Well, first of all, that the study was  
18 done in and of itself, and secondly, in the  
19 particular study there was variations between the  
20 tissue reaction of the individual rats, so it  
21 wasn't as if all of the animals responded in  
22 exactly the same way.

23 So it does indicate that there is  
24 variability to the biologic response to a mesh  
25 material.

1           Q     You would agree with me that with regard  
2     to the Prolift, there is variability with how  
3     different women will react to having the Prolift  
4     in their pelvis; correct?

5                     MR. COMBS: Object to form.

6                     THE WITNESS: Yes.

7     BY MR. SLATER:

8           Q     And that can have a -- rephrase.

9                     And that can be significant in terms of  
10    whether or not the outcome will be positive or  
11    negative; correct?

12          A     That can be a factor. The issue of it  
13    being significant, I mean I -- again, your  
14    definition of significant, my definition of  
15    significant may be different, but it can be a  
16    factor in how the -- of the outcome, yes.

17          Q     I define "significant" to not be  
18    trivial. Okay?

19                    In that definition, you would agree that  
20    the variability in women's responses to having a  
21    Prolift in their pelvis can be significant in the  
22    context of whether or not they will have a good or  
23    bad outcome; correct?

24                    MR. COMBS: Object to form.

25                    THE WITNESS: I don't know that I

1           can say that based on your definition of  
2           significance. It will be a factor. In some,  
3           in some patients it will be more of a factor  
4           than it will be in other patients.

5       BY MR. SLATER:

6           Q     For some women, their response to the  
7       Prolift can be a significant factor in leading to  
8       a poor outcome with a Prolift; correct?

9           A     Poor outcome in terms of what?

10          Q     In terms of complications in their  
11       clinical course.

12          A     I would say that's probably the case,  
13       that if a patient has an excess reaction to the  
14       material, that they could have an increased risk  
15       of complications after the surgery, just like that  
16       would be true in any surgery that we do that  
17       involves a material.

18          Q     Move to strike from "just like" forward.  
19       I'm going to limit my questions to the Prolift  
20       here.

21                       Did you ever see any warning to  
22       physicians or patients that Ethicon was aware that  
23       some women could have a more heightened reaction  
24       to the Prolift that could lead to a higher risk  
25       for complications?

1 MR. COMBS: Object to form.

2 THE WITNESS: I don't recall seeing  
3 a statement to that degree of specificity,  
4 no.

5 THE VIDEOGRAPHER: Excuse me one  
6 second. I'm going to change the tape.

7 MR. SLATER: Okay.

8 THE VIDEOGRAPHER: We're going to  
9 take a necessary break for about a couple  
10 minutes.

11 Going off record at 10:49.

12 (Whereupon, a short recess was  
13 taken.)

14 THE VIDEOGRAPHER: At 10:56 we're  
15 on record, and let the record reflect at  
16 10:49 we went off record, ending tape 1. At  
17 10:56 now, beginning tape 2 in our continuing  
18 deposition of Dr. Horbach.

19 BY MR. SLATER:

20 Q Dr. Horbach, could you look at the prior  
21 page, please, looking at your list of other  
22 materials.

23 Right in the middle of the page, it says  
24 Exhibit 15, letter to Brian Lisa from Mark  
25 Melkerson, and it goes on to a listing of a bunch

1 of different documents.

2 Do you see that?

3 A Yes, I do.

4 Q Can you tell me what, if any,  
5 significance there is to, to the documents listed  
6 there.

7 A To my, the best of my recollection,  
8 there was a discussion among individuals that were  
9 at Ethicon regarding whether or not to proceed  
10 with evaluation and launching of a variation of  
11 the Prolift, and they, and they called this the --  
12 you know, Project Lightning was that particular  
13 decision whether or not to go forward or not with  
14 it, and there were some discussions and cost data  
15 going back and forth regarding timing of the steps  
16 or the process for this project and/or cost issues  
17 that were involved, and they were trying to  
18 determine whether or not to proceed with it.

19 Q And was that significant to you in  
20 forming your opinions in this case?

21 A It was part of the information that I  
22 reviewed. I can't recall if I made a statement in  
23 my report that was specifically -- would reference  
24 that.

25 Q As you sit here now, is there anything



1 within those materials that is of significance to  
2 you in supporting your opinions in this case?  
3 Anything you can point to right now?

4 A No, I don't think so from that  
5 particular memo.

6 Q Do you know whether Ethicon was  
7 concerned with the rates and consequences of  
8 contraction and erosion of the Prolift?

9 A I don't know what they discussed about  
10 that or what they knew about it or their feelings  
11 about it.

12 Q Would, would you agree with me that  
13 based on what you know, that Ethicon should have  
14 been concerned about contraction and erosion with  
15 the Prolift?

16 MR. COMBS: Object to form.

17 THE WITNESS: Yes.

18 BY MR. SLATER:

19 Q You ultimately stopped using the Prolift  
20 in about 2011; correct?

21 A Actually, I went back in my data in my  
22 office, the best we could retrieve it, as we're  
23 doing a practice separation, and it looks like it  
24 was more 2009 that I transferred to the lap --  
25 more of a laparoscopic type of procedure.

1           Q     So am I correct that you basically  
2     stopped using the Prolift in 2009 and transitioned  
3     to laparoscopic abdominal sacral colpopexy?

4           A     That is what I transitioned as my  
5     primary treatment for apical prolapse.

6           Q     And that was based on your assessment of  
7     the risk/benefit profile of the Prolift as  
8     compared to laparoscopic abdominal  
9     sacral colpopexy?

10                     (Discussion was held off the  
11                     record.)

12     BY MR. SLATER:

13           Q     In 2009, you transitioned from the  
14     Prolift -- well, rephrase.

15                     Am I correct that in 2009 you basically  
16     stopped using the Prolift and transitioned to the  
17     laparoscopic abdominal sacral colpopexy based on  
18     your assessment of the risk/benefit profiles for  
19     the alternative procedures?

20           A     Yes.

21           Q     Risk/benefit profile for the Prolift --

22           A     I'm sorry. You, you cut out again at  
23     the beginning of your statement.

24           Q     Oh, that's not good.

25                     In assessing the risk/benefit profile

1 for the Prolift, was one of your concerns on the  
2 risk side the contraction that could occur with  
3 the Prolift?

4 A That was not a factor in my clinical  
5 decision-making regarding the risk/benefits of the  
6 two procedures.

7 Q In assessing the risk/benefit profile  
8 for the Prolift, was one of your concerns on the  
9 risk side erosion?

10 A That was a hypothetical risk, although  
11 we were not really seeing any difference in  
12 erosion rates between sacrocolpopexies and between  
13 Prolift. So for us clinically, that was not a  
14 relevant part of the, of the decision-making.

15 Q What were -- rephrase.

16 When you stopped using the Prolift in  
17 2009, what was the reason you stopped using it?

18 A The -- one of the, one of the balances  
19 of Prolift or different surgical procedures,  
20 whether it's Prolift, sacral colpopexy, other  
21 vaginal procedures without mesh is going to be  
22 what is the specific defect that I need to try to  
23 correct at the time of surgery, and which  
24 procedure is going to be ideally most effective in  
25 simply just the anatomic correction of the

1 problem, followed by the risks associated for the  
2 procedure itself in terms of duration of surgery,  
3 in terms of, you know, interoperative and  
4 post-operative complications, individual medical  
5 history, individual bone structure.

6 There's a whole host of different pieces  
7 of information I use in making a determination of  
8 which procedure I choose to do.

9 Q You were using the same analysis before  
10 you stopped using the Prolift; correct?

11 A Yes, I was.

12 Q So what was it that occurred in 2009 to  
13 where your analysis led you to say, okay, I'm not  
14 going to use the Prolift anymore?

15 MR. COMBS: Object to form.

16 BY MR. SLATER:

17 Q What changed?

18 A One of the biggest changes was that we  
19 were able to transition from doing the sacral  
20 colpopexy as an open procedure to being able to do  
21 it as a laparoscopic procedure.

22 When the sacral colpopexy was something  
23 we performed as an open procedure, it had a then  
24 higher risk of potential complications and  
25 problems that then placed it perhaps at a

1     disadvantage to the Prolift, whereas in our hands,  
2     when we were able to do the laparoscopic  
3     procedure, we were able to reduce some of the  
4     problems that we had seen associated with the open  
5     sacral colpopexy, so that the procedure is now  
6     between sacral colpopexy and Prolift, would, at  
7     least in the majority of my patients, end up going  
8     towards the sacral colpopexy if I was looking to  
9     do an apical support procedure.

10           Q     So if I understand correctly, one factor  
11     in why you stopped using the Prolift in 2009 was  
12     because you felt that the laparoscopic sacral  
13     colpopexy alleviated some of the morbidity that  
14     was associated with the open procedure, and all  
15     things being equal at that point, you felt the  
16     laparoscopic procedure was a better procedure for  
17     your patients than the Prolift.

18                     Do I understand that correctly?

19                     MR. COMBS:   Object to form.

20                     THE WITNESS:   The first part is  
21     correct.   The second part is too much of a  
22     generalization.   My comment was that I felt  
23     in the balance that a laparoscopic sacral  
24     colpopexy provided a better option for my  
25     patients with an apical prolapse.

1                   We're not discussing, you know,  
2           midline, anterior walls, posterior walls, et  
3           cetera. We're simply talking about apical  
4           prolapse.

5   BY MR. SLATER:

6           Q     You told me you stopped using the  
7   Prolift in 2009; correct?

8           A     Correct.

9           Q     You stopped using it for all defects,  
10   whether it was apical, anterior, posterior.

11                   You stopped using it completely;  
12   correct?

13          A     Yes.

14          Q     So if a woman came into your office and  
15   she had an anterior vaginal wall defect like what  
16   Pam Wicker had, from 2009, when you stopped using  
17   the Prolift, forward, you were not recommending  
18   the Prolift to that patient, you were recommending  
19   an alternative procedure; correct?

20          A     Yes, but it wasn't -- she didn't -- her  
21   anterior vaginal wall prolapse was not a,  
22   specifically a midline defect. She had an apical  
23   defect as well, so it would have been that her  
24   apex needed to be supported, and that would have  
25   most likely corrected her anterior vaginal wall

1 relaxation that was coming out the hymen.

2           So I would have recommended a procedure  
3 that would provide apical support, and at that  
4 particular time I felt that the risk/benefits of  
5 laparoscopic sacral colpopexy versus Prolift for  
6 apical support problem would probably be in favor  
7 of the sacral colpopexy.

8           Q     When you had patients come to you in  
9 2009, from the point when you stopped using the  
10 Prolift, with a defect that was not apical in any  
11 way, you were not recommending the Prolift to  
12 them, you were recommending an alternative  
13 procedure; correct?

14           A     So if their apex was fine and it was a  
15 midline anterior/posterior procedure thing, no, I  
16 wasn't recommending the Prolift, but I probably  
17 wouldn't have been recommending the Prolift to  
18 those patients prior to 2009 either.

19                     It's not something that I -- I would  
20 have used it more in patients with a combined  
21 defect rather than a single isolated midline  
22 defect.

23           Q     From your perspective, you felt the  
24 Prolift was not indicated for your patients unless  
25 there was an apical defect?

1           A     Again, it's not that black and white.  
2     It is -- if there was an apical defect that was  
3     manifesting potentially with anterior vaginal  
4     relaxation, or there was an apical defect  
5     manifesting with posterior, you know, prolapse,  
6     and certain other criteria were met, then I would  
7     recommend a Prolift in that particular patient.  
8     If there were different criteria with the same  
9     anatomy, I still may have recommended a, you know,  
10    a different procedure than a Prolift.

11                I mean that's the hard part is that  
12    anatomy of the pelvis, and when you're trying to  
13    do a prolapse operation, you are rarely presented  
14    with a single isolated defect of support. It's  
15    usually a global issue, and so you have to  
16    determine what is the best approach to dealing  
17    with the global components of that patient's  
18    prolapse.

19           Q     From -- well, let me ask you this  
20    question.

21                Where you had patients that did not have  
22    apical defects, what procedure were you -- or  
23    procedures were you recommending?

24                       MR. COMBS: Object to form.

25                       THE WITNESS: It would depend to



1           some extent on the patient's prior history as  
2           well as, you know, other factors that were  
3           played -- other factors that came into  
4           account. I would recommend for some patients  
5           potentially a colpectomy or colpocleisis.  
6           I would recommend for other patients perhaps  
7           a native tissue repair. I would recommend  
8           for other patients perhaps a Prolift.

9   BY MR. SLATER:

10           Q     Did you perform Prolifts on women  
11           without apical defects?

12           A     Probably. Again, I'd have to go back,  
13           but probably.

14           Q     If you did, it was very, very few;  
15           correct?

16           A     I'm not going to say very, very few. I  
17           can't give you the specific numbers.

18           Q     Do you remember any patient that did not  
19           have an apical defect where you performed a  
20           Prolift on that patient?

21           A     An individual patient off the top of my  
22           head, no, but I only remember a few of the  
23           patients specifically that I did Prolifts in,  
24           regardless.

25           Q     Well, whether you can remember the name

1 of the patient or not, do you remember any  
2 particular patient or any specific instance where  
3 you performed a Prolift on a patient who did not  
4 have an apical defect?

5 A Yes, I have done that.

6 Q How many times? How many times?

7 A I can't tell you that number.

8 Q It would be very few; correct?

9 A I can't tell you that number.

10 Q It would probably be less than ten  
11 patients; correct?

12 A I can't answer that question.

13 Q You still feel that native tissue repair  
14 is a reasonable procedure; correct?

15 A For which part?

16 Q Women with prolapse.

17 A Depends on what part of their pelvis is  
18 prolapsing.

19 Q As a general proposition, you would  
20 agree with me that native tissue repair is a  
21 reasonable alternative; correct?

22 MR. COMBS: Object to form.

23 THE WITNESS: It is an alternative.

24 In some patients it's more reasonable than  
25 others.

1 BY MR. SLATER:

2 Q Okay.

3 After you stopped using the Prolift in  
4 2009, if a woman did not have an apical defect,  
5 what were the options that you were offering?

6 Just want to know the list of procedures  
7 you would offer to that patient.

8 A Without an apical defect?

9 Q Yes.

10 A So it's midline only.

11 I would -- most likely it would be  
12 either a -- if it was a nonsexually active  
13 patient, it might be a colpectomy, especially if  
14 the anterior wall was a large prolapse or there  
15 was significant dilation of the introitus or the  
16 patient had failed prior surgery. Alternatively,  
17 I would probably use a native tissue repair. I  
18 don't think I was using biologic grafts at that  
19 particular time period.

20 Q Have you since begun to use biologic  
21 grafts?

22 A I tend not to, since my experience with  
23 using them, and I can't remember whether it was  
24 pre-2009 or post, was that the biologic grafts  
25 really don't provide any additional benefit for

1 prolapse repairs, and in the posterior vaginal  
2 wall, they actually can worsen the outcome of the  
3 prolapse repair.

4 Q So after 2009, if you had a patient with  
5 no apical defect, you would either offer the  
6 patient native tissue repair, or if the woman was  
7 not sexually active or had some other very extreme  
8 medical history, you would offer a colectomy; is  
9 that a good understanding?

10 A Yes, and actually I would, I would put  
11 Prolift on the options that I would offer her. It  
12 doesn't -- they may not have chosen Prolift, but I  
13 certainly would have still counseled them  
14 regarding that being an option.

15 Q Well, I thought you stopped using it  
16 completely.

17 A My decision to stop using it isn't  
18 necessarily solely going to be my decision. If I  
19 counsel a patient regarding treatment options and  
20 the pros and cons of treatment options, and the  
21 patient chooses not to have that procedure, then  
22 I'm not going to have a record that I did the  
23 procedure, but that doesn't mean that I didn't  
24 offer it to the patient.

25 Q Well, after the point -- well, let me

1 ask you this.

2 When in 2009 did you perform your last  
3 Prolift?

4 A I don't remember exactly. We tried to  
5 print it out, and I couldn't -- I don't remember  
6 exactly.

7 Q But it's on -- it's documented in your  
8 office?

9 A The hard part is we don't know that that  
10 is the complete documentation because of the split  
11 we're doing in our practice and the ability to go  
12 back into the computer system and try to retrieve  
13 all of the information. There's -- the  
14 information is in several different sites, and  
15 some of it is more retrievable than others.

16 Q There came a point in 2009 where you  
17 performed your last Prolift procedure.

18 You don't know the exact date, but it  
19 occurred in 2009; correct?

20 A Correct. I could not find any record  
21 for having performed a Prolift in 2010. Again, it  
22 might have happened. I just couldn't find any  
23 documented record.

24 Q Based on your recollection -- well,  
25 rephrase.

1                   Is your recollection consistent with  
2   your review of the documentation in your office  
3   that the last Prolift you performed was in 2009  
4   sometime?

5           A       Well, actually my recollection probably  
6   wasn't consistent with that documentation, because  
7   in my previous deposition I said that I thought I  
8   had continued to perform Prolifts up until 2011.  
9   So obviously my recollection was that I continued  
10   to perform them for a longer period of time, but I  
11   could not find documentation for 2010 and 2011  
12   with the system that I have available.

13          Q       After the, the date, whatever that was,  
14   in 2009 when you performed your last Prolift  
15   procedure, did you continue to offer the Prolift  
16   as an option to patients?

17          A       Yes.

18          Q       Did any of those patients say, okay, I  
19   want a Prolift?

20          A       Obviously not, since I didn't do it past  
21   that point.

22          Q       If a patient had said yes, I want a  
23   Prolift, would you have performed it, or would  
24   it -- would you have referred them to a different  
25   surgeon?

1           A     It depends on whether I think the  
2     Prolift would be an appropriate procedure for  
3     them.

4                     I do recall one specific patient where  
5     the family, the daughter wanted the patient to  
6     have a Prolift, and I did not think that it was an  
7     appropriate choice for that individual patient, so  
8     I, I said that I would not do that, and if they  
9     wanted a Prolift, they could go elsewhere.

10          Q     What happened?

11          A     They went elsewhere but then turned  
12     around and came back to me, because they were told  
13     by everybody else that I was the best one to do  
14     their surgery, and I did not do her surgery.

15          Q     What was the consent discussion -- well,  
16     rephrase.

17                     When you were consenting patients in  
18     2009 before you stopped using the Prolift, what  
19     were the risks that you were telling the patients  
20     about the Prolift?

21          A     I'm going to isolate this to more  
22     specifically the choice of, let's say, Prolift as  
23     a material versus sutures versus sacrocolpopexy,  
24     et cetera, because the typical risks of, you know,  
25     injury to the bladder, injury to the rectum, you

1 know, all the kind of normal surgical things and  
2 stuff, we're going to assume that that's already  
3 part of the factor.

4 Is that okay?

5 Q That's fine.

6 The general surgical risks that would be  
7 consistent from procedure to procedure, just  
8 because you're operating, I don't need you to go  
9 through those, because we understand those to be  
10 the same regardless of what procedure.

11 A Okay.

12 So if I was counseling a patient  
13 regarding a choice of a surgical procedure and  
14 whether Prolift was appropriate for her or not, I  
15 would first start by discussing with her what her  
16 anatomic defect is, and therefore, which --

17 Q I don't mean to interrupt you, Doctor.  
18 I -- this -- my question is very simple.

19 I just want to know the list of risks  
20 you were counseling patients about with regard to  
21 the Prolift in 2009, aside from those general  
22 surgical risks that would apply regardless of what  
23 type of surgery you're doing just because they're  
24 surgical risks in general.

25 I just want to know the risks, the list



1 of risks.

2 MR. COMBS: Object to form.

3 THE WITNESS: I would say that  
4 failure of the procedure; reaction to the  
5 material, including erosion into the vagina,  
6 bladder, rectum that could require future  
7 surgery; pain; scarring; risk of stress  
8 urinary incontinence post-operatively; risk  
9 of irritating voiding, symptoms of urgency,  
10 frequency.

11 When we talk about post-operative  
12 pain issues, you know, we talk about  
13 post-operative pain, whether it's a surgical  
14 pain, you know, around the time of surgery,  
15 whether it's long-term pain from scarring or  
16 whether it is dyspareunia, depending on  
17 whether or not the patient is sexually  
18 active.

19 I'm trying to remember if there was  
20 anything else on the list that I would  
21 specifically say. To the best of my -- I  
22 mean I may remember another one, but to the  
23 best of my recollection, that was the bulk of  
24 it.

25

1 BY MR. SLATER:

2 Q In 2009, if a woman was under the age of  
3 60 and sexually active, were you cautious about  
4 whether or not to recommend a Prolift?

5 MR. COMBS: Object to form.

6 THE WITNESS: I would still, I  
7 would still have Prolift as a possible option  
8 on the, on the list of choices.

9 I think what you may need to  
10 understand also is that I don't tell a  
11 patient what surgery she should have. That  
12 isn't my role. My role is to present her  
13 with the potential options for correcting her  
14 problem, and the pros and cons of each of  
15 those options, and depending upon the  
16 individual goal that the patient has for her  
17 surgery, she may choose one option over  
18 another, even if it wasn't maybe my first  
19 choice for her.

20 If I feel that the option is  
21 absolutely not a good choice for her, as in  
22 this one particular patient, I won't  
23 recommend it or I wouldn't put it on the  
24 table or I wouldn't agree to do it, but I  
25 will at times do a procedure in a patient

1           where it's not necessarily my first choice  
2           for that patient, but because -- based on my  
3           totally objective position as a physician,  
4           but because the patient has different goals  
5           perhaps than what I might have, they are  
6           willing to take more or less of a risk, and  
7           they choose a different alternative.

8       BY MR. SLATER:

9           Q     When you counsel a patient, one thing  
10          you do is you say -- you'll tell the patient what  
11          you think are the reasonable options for her  
12          prolapse condition; correct?

13          A     Yes.

14          Q     It's common for the patient to say,  
15          okay, those are the options, but Doctor, which one  
16          do you recommend is the option that you think is  
17          best for me, and can you explain to me why?

18                  That, that's common; right? They want  
19          the recommendation; right?

20          A     I'm asked that question. I rarely give  
21          them an answer that is where I say this is what I  
22          would do. I rarely say that to a patient.

23          Q     Okay.

24                  Let's take a woman who is under the age  
25          of 60, she's sexually active, you offer the

1 Prolift as one of the options.

2                   Were you telling a patient with that  
3 profile, however, you need to be cautious because  
4 of the risks to a sexually active woman with a  
5 Prolift? Was that something that you would  
6 include in your discussion in 2009?

7                   MR. COMBS: Object to form.

8                   THE WITNESS: Yes. I would do that  
9 whether she was under 60 or over 60.

10 BY MR. SLATER:

11           Q     Okay.

12                   When you stopped using the Prolift in  
13 2009, did your partners in your medical practice  
14 also stop using it?

15           A     I don't recall when they converted to  
16 doing laparoscopic as their primary method. I do  
17 think that one in particular did continue using  
18 the Prolift for an additional period of time,  
19 because he was not experienced with doing  
20 laparoscopic surgery, so he did continue using  
21 transvaginal mesh type procedures for a longer  
22 period of time.

23           Q     You actually published an article  
24 regarding laparoscopic sacrocolpopexy in 2012;  
25 correct?

1           A     Yes, that was published. One of our  
2     fellows had gone through some of the information  
3     from our practice, yes.

4           Q     One of the things it says in the article  
5     is, "Our suture extrusions were of minimal  
6     clinical significance, as most were asymptomatic  
7     and none required reoperation."

8                     That was, that was one of the things  
9     that was stated in that article; correct?

10          A     I assume that you're reading it, yes. I  
11     mean I don't have it in front of me.

12          Q     It's on page 116 of the article, just  
13     for the record.

14          A     Do you have the -- do you have that as  
15     an exhibit?

16          Q     No, I don't. I'm just going to ask you  
17     a quick question.

18                     The reason -- well, rephrase.

19                     In your experience, a suture extrusion  
20     is usually of minimal clinical significance;  
21     correct?

22                             MR. COMBS: Object to form.

23                             THE WITNESS: Yes.

24     BY MR. SLATER:

25          Q     In balance, if there's an extrusion of a

1 suture as compared to an extrusion of Prolift  
2 mesh, it's more likely that the Prolift mesh  
3 extrusion is going to be more clinically  
4 significant; correct?

5 A Depends on the size of the mesh  
6 extrusion. Some, some mesh extrusions may be  
7 totally asymptomatic, and others may be  
8 symptomatic.

9 Q General proposition, you would agree  
10 that an extrusion of Prolift mesh will be more  
11 clinically significant than an extrusion of a  
12 suture; correct?

13 A Again, it depends upon if you're talking  
14 about the same size of mesh that's -- the same --  
15 a suture is going to be a certain size. If you're  
16 talking about a mesh erosion that's the same size,  
17 then they are both going to be probably fairly  
18 similar in their clinical manifestation, but if  
19 you're talking about a suture versus a larger mesh  
20 erosion, then the larger mesh erosion will  
21 typically be more clinically significant.

22 Q Okay.

23 In your list of materials, the "Other"  
24 section, on the page where we -- I had just been  
25 asking you about, fourth from the top is a

1 clinical expert report regarding the Prolift,  
2 dated July 2, 2010.

3 Was that document of significance to you  
4 in forming your opinions in this case?

5 A I would have to pull the document before  
6 I could say specifically what the significance of  
7 that document was. It was part of what I looked  
8 at in forming my opinion.

9 Q As you sit here now, is there anything  
10 about that document that you can say, you know,  
11 this was significant for this reason, I'm relying  
12 on it for this reason for one of my opinions?  
13 Anything like that you can tell me as you sit here  
14 now?

15 A Without pulling the article, the  
16 document, I cannot say that.

17 Q I saw no references to that document in  
18 your report.

19 Is that accurate, based on your  
20 knowledge of your report?

21 A Not necessarily, because I didn't really  
22 reference any of the -- I referenced very few of  
23 the articles specifically by author, name, et  
24 cetera.

25 Q Do you know what a clinical expert

1 report is?

2 A In this particular patient or this  
3 situation? I'm trying to remember the specifics,  
4 but I believe I recall it. I think perhaps --

5 Q What is a clinical expert report?

6 A Just like what I've -- you know, a  
7 report -- like what -- how can I explain it other  
8 than it's a person who is an expert that's giving  
9 a report on a particular product?

10 Let me see if I can pull that particular  
11 article so that I can talk more --

12 Q I'm not asking you to pull it. Please  
13 don't. Doctor, I'm asking you not to pull it out,  
14 please.

15 A Then I can't discuss it with you.

16 Q Okay, and that may be so.

17 Do you know what the purpose of a  
18 clinical expert report is within Ethicon?

19 A No, I don't know what Ethicon uses that  
20 for.

21 Q And as you sit here now, there's nothing  
22 you can tell me about the July 2, 2010 clinical  
23 expert report for the Prolift? There's nothing  
24 you can tell me about it at all as you sit here  
25 now; correct?



1           A     I told you that I can't answer that  
2     question without retrieving the document.

3           Q     Did you prepare for this deposition  
4     today?

5           A     I did, yes.

6           Q     How much time did you spend preparing  
7     overall for this deposition?

8           A     In the --

9           Q     Not just today, but total.

10          A     Well, it depends on what -- again, it  
11     depends on what you mean.

12                     If you're talking about preparing the  
13     actual reports for the deposition that were done a  
14     year ago, that is one bulk of time. If you're  
15     talking about how much time I spent to prepare in  
16     the recent past, you know, recently for this  
17     particular deposition, that's going to be a  
18     different amount of time.

19          Q     Why don't you tell me both.

20          A     So the amount of time that I spent prior  
21     to, in drafting, in reviewing this information and  
22     drafting the reports, probably is going to be  
23     close to 80 to 100 hours. I don't recall right  
24     off the top of my head.

25                     The amount of time that I have spent

1 more recently within the last couple weeks  
2 preparing for this deposition probably approaches  
3 around 50 hours.

4 Q As part of that preparation, did you  
5 review the documents listed in this list of  
6 materials?

7 A Did I go back and reread them? Not --

8 Q Any of them.

9 A Not -- I did not reread all of the --  
10 yes, I did read some of them again, but I didn't  
11 read all of them again.

12 It was primarily based -- I read  
13 primarily clinical information, such as the  
14 medical record reports, transcripts of  
15 depositions. I reread those rather than, per se,  
16 the articles.

17 Q Do you know whether the IFU for the  
18 Prolift was changed over the course of time to add  
19 risks --

20 A Yes.

21 Q -- or warnings?

22 A Yes, it was.

23 Q Do you know why that happened?

24 A I can only make an assumption.

25 Q From your review of the materials that

1 you looked at, do you know why it occurred  
2 specifically, not an assumption, but factually why  
3 the changes were made?

4 A I don't have an internal Ethicon  
5 document that says we are making these changes in  
6 the IFU because of this, no. I have not seen a  
7 document to that effect.

8 Q Are you aware of whether or not the  
9 discussion of risks and benefits in the patient  
10 brochure for the Prolift was changed over the  
11 course of time?

12 A Yes, it was.

13 Q Do you know why?

14 A Again, I would be making an assumption  
15 of why they made the change.

16 Q Based on a review of any documents or  
17 deposition testimony as to why those changes were  
18 made?

19 A I told you that I didn't review the  
20 depositions of the Ethicon employees, so I can't  
21 certainly do it based on that, and I don't recall  
22 having seen a specific written document, email, et  
23 cetera, about why they specifically made the  
24 changes in the patient brochure information.

25 Q The depositions of Ethicon witnesses

1 that are listed on your list of materials, you did  
2 not review those; correct?

3 A Yes. That's what -- we said that at the  
4 very beginning. I did not.

5 Q Okay.

6 Did anybody tell you why those materials  
7 were being listed on -- well, let me ask you this.

8 Did you prepare this list, or did  
9 counsel prepare this list?

10 A This was a list that was, that was put  
11 together based on both counsel and myself.

12 Q When you saw the depositions of Ethicon  
13 witnesses listed on here that you had not read,  
14 did you question that or suggest to take their  
15 names off since you hadn't reviewed those  
16 materials and since you hadn't looked at them?

17 A No, I did not suggest that.

18 Q Up until right now, have you ever made  
19 an effort on your own part to review internal  
20 Medical Affairs or other documents from Ethicon to  
21 try to get an understanding of what their  
22 knowledge was with regard to the Prolift?

23 A I guess the simple answer would be no, I  
24 have not contacted them and asked them for  
25 specific documents that were internal documents.

1           Q     You understood that if you wanted to,  
2     you could have asked counsel to give you internal  
3     Ethicon documents so you could have an  
4     understanding of what Ethicon's internal  
5     information was?

6                     You knew you could have asked for that  
7     if you wanted to; correct?

8                     MR. COMBS:   Object to form.

9                     THE WITNESS:   Yes.

10    BY MR. SLATER:

11           Q     You chose not to; correct?

12           A     Yes.

13           Q     Let's look at Exhibit 5, if we could.

14                     This is a document that we were provided  
15     about two days ago titled "Supplemental Expert  
16     Report General and Specific to Pamela Wicker."

17                     What is this document?

18           A     I was provided additional medical  
19     records and deposition testimony on very short  
20     notice that I used in confirming my opinions or  
21     adding to my opinions that I had previously had in  
22     this particular case.  The documents also provided  
23     me an update regarding her medical treatment,  
24     medical visits since the time that I had done the  
25     IME.

1                   So I was asked by counsel to provide a  
2   brief additional statement based on the additional  
3   information that I reviewed that was sort of --  
4   some of it which was sort of hot off the press,  
5   including Ms. Wicker's recent deposition.

6                   So that's what --

7           Q       When were these materials, when were  
8   these materials provided to you that you based  
9   this supplemental report on?

10          A       Many of them within the last -- less  
11   than a week.

12          Q       What materials did you actually review  
13   to write this supplemental report?

14          A       Do you want to start with -- well, let's  
15   see. Where shall we start with? I can just start  
16   with medical records, I assume, I guess.

17                   Some of this information is redundant  
18   from the other list, but the medical records that  
19   I reviewed was her updated medical records, the  
20   issues of having been seen for the headache  
21   evaluation, the more recent information from  
22   Dr. Raz.

23          Q       Let me ask you this.

24                   Are you able to -- well, rephrase.

25                   Attached to your one-page supplemental

1 report is a list of materials from pages 2 through  
2 6.

3 What I would like to know is which  
4 materials listed on pages 2 through 6 did you  
5 actually read as support for this supplemental  
6 report.

7 A The --

8 Q If we go to page 2, let's start on page  
9 2 on the literature list.

10 Did you read any of those materials in  
11 order to write this supplemental report?

12 A These were -- well, some -- most of the  
13 materials were read prior to even the supplemental  
14 report. There are a couple things that, you  
15 know -- the Lee article, which was recent, I read  
16 just recently, within the last couple days.

17 Q Are you saying you've read every bit of  
18 the literature on page 2?

19 A I believe so. At one point or the  
20 other, yes.

21 Q Well, let me ask you this.

22 You wrote a supplemental report where  
23 you gave I guess clarification and, and -- on your  
24 opinions.

25 A Mm-hmm.

1           Q     You don't cite any of this medical  
2     literature in that report; correct?

3           A     No. I was given very short amount of  
4     time to try to provide this, and I have an  
5     extremely busy clinical practice, so the ability  
6     on the short notice that I was given as well as  
7     the short notice of receiving some of the  
8     documents, i.e., Pam Wicker's deposition from  
9     Monday, it would have been pretty much impossible  
10    for me to have been able to write a report and  
11    cite specifically each thing that was included in  
12    that report.

13          Q     Here is what I want to understand.

14                You said you were provided materials  
15    less than a week ago. You reviewed those specific  
16    materials, wrote this supplemental report, and it  
17    was served on me a couple days ago.

18                That's what occurred; correct?

19          A     Correct.

20          Q     I want to know what are the materials  
21    you actually read in the last less than a week to  
22    write this supplemental report, and I'll start you  
23    off.

24                It says you read Dr. Raz's trial  
25    deposition.



1 A Yes.

2 Q So that's something you read?

3 A Yes.

4 MR. COMBS: Object to form.

5 BY MR. SLATER:

6 Q You've told me that you read Pam  
7 Wicker's deposition from earlier this week.

8 So you read that; correct?

9 A Yes.

10 Q Did you read both of those documents in  
11 their entirety?

12 A Yes.

13 Q Have you watched the video of Dr. Raz's  
14 trial testimony or have you just read the  
15 transcript?

16 A I have just read the transcript.

17 Q Other than reading Dr. Raz's trial  
18 testimony and reading Mrs. Wicker's testimony from  
19 Monday, what else did you read in the last week in  
20 preparation for writing this supplemental report?

21 A I read Wallace's deposition. I read, to  
22 the best of my recollection, I'm not sure, the,  
23 the three articles that are by Dr. Tu, I guess,  
24 T-U, one or a combination of those.

25 Q Oh, the three articles by Dr. Tu?

1           A     Tu, yes, one or the other of those. I  
2     think I briefly looked at Ozel. That -- I mean  
3     some of these things had been -- you know,  
4     obviously I had read previously, but I think I  
5     looked briefly at that article again.

6                     I looked briefly at the Nygaard article.

7           Q     That's the "(2013) Long-term  
8     Outcomes" --

9           A     Right.

10          Q     -- "following ASC"?

11          A     Yep. That's the only one that's listed  
12     here.

13                    I looked at the Lee article, as we  
14     talked about. I'm trying to remember. I looked  
15     at one of the -- I'm going to kill his name --  
16     Jacquetin articles. I don't remember if that's,  
17     if it's specifically this one or not, but I  
18     remember reading more recently one of his articles  
19     or her articles, because I can't pronounce the  
20     name. I think I read the Barber article. The  
21     Azar article.

22                    Yeah, those are the best of my  
23     recollection that I had either reviewed prior to  
24     this. Only -- I mean the Lee article was one of  
25     the ones that was, you know, absolutely brand new

1 kind of thing.

2 Many of these I've had previously and  
3 sort of looked back at. The Pelvic Pain One  
4 issues were a part of it. I mean I've even pulled  
5 articles where information -- you know, last night  
6 that isn't totally on this list, because I haven't  
7 had the ability to put it on the list, so . . .

8 The medical record -- I'm sorry -- the  
9 medical record part, the parts of the medical  
10 record that were new since her -- since I did the  
11 IME, so that would include the Newman, Nathan  
12 Newman reports.

13 Q Okay.

14 A From that stuff. The Mueller more  
15 recent one. I don't see it, but it may be under a  
16 different name, but in terms of starting the beta  
17 blockers. The Raz report from March 2013. There  
18 were two Mueller visits. The headache clinic  
19 visits that she had.

20 The visits -- the foot -- she had an  
21 evaluation for some left foot pain in, from March  
22 of 2013 and April 2013, and she was seen by an  
23 orthopedist for that. Follow-up headache clinic  
24 issues. Follow-up headache clinic issues, and  
25 Soundview Medical in September for her evaluation

1 for hypothyroidism.

2 Those are the things I've specifically  
3 listed here.

4 Q Now let's go to the list of "Other" on  
5 page 5 of 6.

6 Did you read any of these materials in  
7 the last week in preparation of this supplemental  
8 report?

9 A Probably not, but let me look through.

10 The ACOG practice bulletin March 2004  
11 and 2011. I think that's probably -- I mean I  
12 went back and looked, you know, briefly at the  
13 IFUs and the patient brochure information and some  
14 of the educational information, but I can't tell  
15 you which of those umteen things listed there it  
16 is, because it was just very, you know, flipping  
17 through them, looking for stuff.

18 Again, there may be --

19 Q This list -- I'm sorry. Go ahead.

20 A There may be additional new medical  
21 records. There was the one -- the Lawrence Newman  
22 I think is one of her newer physicians.

23 So there may be additional records that  
24 I looked at from, care from -- whatchamacallit --  
25 last year after my IME onward, but I just didn't

1 necessarily make a notation in my handwritten  
2 notes, so there may be some additional things on  
3 this one here.

4 Q This supplemental report does not  
5 reference any medical literature; correct?

6 A Correct.

7 Q This supplemental report does not list  
8 or reference any expert reports; correct?

9 A Correct.

10 Q This supplemental report references the  
11 deposition of -- the trial deposition transcript  
12 of Dr. Raz and the transcript of Ms. Wicker's --  
13 Mrs. Wicker's deposition this week; correct?

14 A Correct.

15 Q It does not reference any other  
16 depositions; correct?

17 A Well, the reference to Dr. Moldwin  
18 was -- can -- is partially from deposition and  
19 partially from medical record.

20 Q Okay.

21 There's no other references to any  
22 deposition testimony; correct?

23 A There's not a reference to, although I  
24 did -- I'm just trying to remember which ones I  
25 have looked at further.

1                   There's --

2           Q       Move to strike.

3                   There's no other reference to any  
4   deposition transcripts in the supplemental report;  
5   correct?

6           A       Correct, although I can add to the  
7   supplemental list that I did re-review a portion  
8   of Dr. Harris' deposition.

9                   I'm trying to remember who else. There  
10   may be additional, but I don't recall right now.

11          Q       You listed certain specific facts from  
12   certain medical records; correct?

13          A       Yes.

14          Q       The list of other documents on pages 5  
15   and 6, none of those are referenced in your  
16   supplemental report; correct?

17          A       They're not specifically referenced in  
18   it. They are information that I used.

19          Q       Move to strike.

20                   None of the documents on page 5 or 6  
21   attached to this supplemental report are  
22   referenced in the supplemental report; correct?

23          A       Correct.

24          Q       On pages 5 and 6, there were lists of  
25   anatomical videos, professional education slide

1 decks, IFUs, patient brochures.

2 None of them are referenced in the  
3 supplemental report; correct?

4 A I already answered that question.  
5 Correct.

6 Q And as you sit here now, you couldn't  
7 tell me which of these you may have glanced at in  
8 the last week before writing this report; correct?

9 A Are you talking about from page, from  
10 pages 5 and 6?

11 Q Right.

12 A From the anatomic videos and the Prolift  
13 education ones, I can't tell you which of those I  
14 specifically looked at. I can tell you that the  
15 ACOG practice --

16 Q That wasn't my question. Doctor, I  
17 didn't ask about anything else. I didn't ask  
18 about ACOG.

19 A You asked me about pages 5 and 6.  
20 ACOG --

21 Q I asked you about the, the videos and  
22 the professional education slide decks. That's  
23 all I asked about in that question --

24 A I misunderstood --

25 Q -- and you answered that.

1           A     I misunderstood the question.

2           Q     That's fine.

3                     This list, was this prepared by you or  
4 by counsel?

5           A     Both.

6           Q     The list of "other" materials, that was  
7 prepared by counsel; correct?

8           A     Correct. Oh, actually, counsel plus me  
9 providing them some of the references.

10          Q     You provided the references for the ACOG  
11 practice bulletins in March '04 and April 2011?

12          A     Correct, and there were some additional  
13 references that I provided them, but they're not  
14 on the list. I just didn't have time to get them  
15 on the list.

16          Q     Did you prepare the list of medical  
17 records?

18          A     That list I did not specifically type in  
19 myself, no. They typed that in.

20          Q     On page 3, the list of expert reports,  
21 was that prepared by counsel?

22          A     They did the typing, yes.

23          Q     The list of depositions, that was  
24 prepared by counsel?

25          A     They did the typing, yes.



1 Q And you told me what you did, what you  
2 did review, which means you did not review the  
3 Barbolt, Kammerer, Weisberg --

4 A Hang on.

5 Q -- Weber or --

6 A Can you --

7 Q Did I go too fast?

8 A So you're talking about depositions and,  
9 and exhibits?

10 Q Yeah, on page 3, am I correct you did  
11 not read Barbolt, Kammerer, Weisberg, Weber or  
12 Hinoul June 27, 2013?

13 A I did not read them within this last  
14 week in preparation for this, no. I had  
15 previously read Weber's.

16 Q You have not read the others, Barbolt,  
17 Kammerer, Weisberg and Hinoul? You haven't read  
18 those transcripts; correct?

19 A Correct.

20 Q Were you ever shown the clinical expert  
21 report that Pete Hinoul prepared in 2012 for the  
22 Prolift + M?

23 A I don't recall.

24 Q I don't see it listed anywhere. You  
25 don't remember seeing it; correct?

1           A     I said I don't recall one way or the  
2     other.

3           Q     I'll come back to this.

4                     Well, let me ask you about this,  
5     actually. In the list of literature, there are  
6     three references with an author whose last name is  
7     Tu, T-U.

8           A     Yes, we talked about those before.

9           Q     Have you -- did you read each of those  
10    articles?

11          A     I read the article -- I can't say that I  
12    read all three of them in their entirety, but I  
13    read portions of I believe all three.

14          Q     What was of significance to you, if  
15    anything, from those articles?

16          A     The discussion regarding the pelvic pain  
17    issues and approaches to pelvic pain.

18          Q     Is that what you mean by that?

19          A     I'm sorry? I said --

20          Q     New question.

21                     When you -- when you say "approaches to  
22    pelvic pain," do you mean approaches to treatment  
23    to pelvic pain?

24          A     Approaches to both evaluation and  
25    treatment of pelvic pain in a patient that might

1 be then referable -- or not might, but that is  
2 referable to some of the issues I think going on  
3 in Mrs. Wicker's situation.

4 Q You would agree with me that Pam Wicker  
5 has had chronic pelvic pain since the time the  
6 Prolift was placed in her body; correct?

7 MR. COMBS: Object to form.

8 THE WITNESS: She has reported  
9 episodic pelvic pain. At times she has  
10 reported not having pain. So if you use the  
11 definition of pain that's occurred for  
12 greater than a six-month duration, then that  
13 would -- her symptoms would fall into that  
14 definition.

15 THE VIDEOGRAPHER: Excuse me one  
16 second, counselor. I have to change tapes.  
17 At 11:56, off record, ending disc 1 in our  
18 continuing deposition of Dr. Horbach.

19 MR. COMBS: Let's take a break for  
20 a couple minutes.

21 (Whereupon, a short recess was  
22 taken.)

23 THE VIDEOGRAPHER: Our time now is  
24 1:07, and we are on record, beginning disc 2  
25 in our continuing deposition of Dr. Horbach.

1 THE WITNESS: Disc 3.

2 THE VIDEOGRAPHER: Well, it's  
3 actually disc 2, but thank you.

4 BY MR. SLATER:

5 Q From the point you received the  
6 materials that you relied on for the supplemental  
7 report to the point when you authored the report,  
8 how much time did you spend on the review and the  
9 authoring of the report?

10 A Sorry. I'm just trying to add up.  
11 Probably close to 20-ish hours.

12 Q What day was it that you actually  
13 received these materials?

14 A I received some of the materials on  
15 Monday and I received some of the materials on  
16 Tuesday, and I'm trying to remember whether I had  
17 anything additional come on Wednesday before I was  
18 drafting it. I actually had to cancel half a  
19 day's worth of surgery to be able to draft this  
20 given the time constraints, and so I'm actually  
21 operating tomorrow morning as a result.

22 Q So you received the materials that you  
23 relied on to write the supplemental report Monday,  
24 Tuesday, possibly into Wednesday, you drafted the  
25 report, and it was served on me on Wednesday;

1 correct?

2 A Yes.

3 Q And you spent about 20 hours; correct?

4 A Reviewing -- again, reviewing the new  
5 information that came and going back and reviewing  
6 some of the older information as well in  
7 preparation for this.

8 Q The list of expert reports on page 3, I  
9 don't remember if I asked you. Did you read  
10 those?

11 A Well, I read mine again, and I don't  
12 think -- I don't recall that I reread Dr. Weber's.  
13 The other ones weren't -- I didn't read -- they  
14 were sort of less relevant. I mean granted with  
15 more time I might have, but I didn't.

16 Q So the only two depositions on that list  
17 that you've read -- rephrase.

18 So the only two expert reports on that  
19 list on page 3 that you have read are Dr. Weber's  
20 and yours; correct?

21 A I think previously, a year plus ago,  
22 that I read either all or part of Dr. Murphy's.

23 Q Did you make an effort to read all of  
24 the articles written by the French TVM group with  
25 regard to the Prolift?

1           A     Prior to my expert report a year ago, I  
2     had made an effort to read most, if not all. I  
3     have not subsequently pulled those specific --  
4     that specific group of investigators' newer  
5     literature.

6           Q     Here's what I want to understand very  
7     clearly. As you sit here now, are you able to  
8     confirm for me whether or not the articles that  
9     are listed on your two lists, that those that were  
10    written by members of the French TVM group  
11    constitute all the articles written by that group  
12    regarding the Prolift? Do you know whether or not  
13    this covers all the Prolift articles by those  
14    doctors?

15                   MR. COMBS: Object to form.

16                   THE WITNESS: No. I'm sure -- I'm  
17     sure it doesn't. I mean there are other ones  
18     that I've seen just in doing, you know, a  
19     literature search or something else, that  
20     I've seen, you know, a particular article  
21     that I know is from that group, and haven't  
22     necessarily pulled that article within the  
23     last week as I was going through for this,  
24     so -- but I know there's additional articles  
25     by the French group.

1 BY MR. SLATER:

2 Q Let me, let me ask the question very  
3 simply.

4 As you sit here now, you know that there  
5 are articles written by members of the French TVM  
6 group with regard to the Prolift that you have not  
7 read; correct?

8 A Correct.

9 Q Did you ever make an effort to ensure  
10 that you would read all of the articles written by  
11 the French TVM group with regard to the Prolift?  
12 Did you ever set out to do that? Was that ever  
13 one of your goals as an expert in this case?

14 A It was one of my goals to read those  
15 articles that were done by the French group prior  
16 to, you know, the 2008/2009 time period, because  
17 that was most relevant with what was known in the  
18 literature at the time.

19 Q Why is that important?

20 A Because you make a decision to some  
21 extent, at least from a clinical standpoint, of  
22 whether you choose to offer a treatment to a  
23 patient, discuss the types of complications  
24 associated with the patient, based on the  
25 information that is available, you know, at the

1 time that you're making those decisions and  
2 counseling the patients, et cetera.

3 You know, we may have data that comes  
4 out five years later, ten years later that there  
5 is potentially another issue or new factors.  
6 That, that information wasn't necessarily  
7 available at the time. It may change to some  
8 extent what you choose to do or not do, but it  
9 isn't necessarily as relevant to the information  
10 and the decisions that were made at the time when  
11 the Prolift was placed in this patient.

12 Q Do you learn things about the risks of  
13 the Prolift after October 20, 2008, the day of Pam  
14 Wicker's surgery, that you felt were of  
15 significance to you in doing a risk/benefit  
16 profile for the Prolift?

17 MR. COMBS: Object to form.

18 THE WITNESS: I learned -- the, the  
19 information that came out around that time  
20 period -- and I can't tell you whether it was  
21 right before that, before that October time  
22 period in 2008, must have been right around  
23 there -- was really more the information that  
24 came out from our article that was published.

25 It was published in 2009, but the



1 data was being gathered around that time,  
2 sort of late 2000 -- or mid-2008, that that  
3 manuscript and the abstract was being  
4 prepared to submit to AUGS.

5 So that information was coming out  
6 just around the time of Pam Wicker's surgery,  
7 and the information did affect to some degree  
8 my counseling of the patients or going back  
9 and looking and thinking would I approach a  
10 patient differently or not with that  
11 additional information.

12 I don't think that there has been  
13 information that's come out really  
14 subsequently that has made, you know,  
15 major -- made -- would make a major change in  
16 my decision about how I choose to do Prolift  
17 or not, because the, the risks that have come  
18 out subsequently were risks that we knew  
19 about at the time Prolift was being used.

20 BY MR. SLATER:

21 Q You told me, if I understand correctly,  
22 that when you were writing and then ultimately  
23 publishing your article -- and you're talking  
24 about the July 2009 article; correct?

25 A The one that is authored by Matt Aungst?

1 Q Yes.

2 A Okay, yeah, I didn't know that it was  
3 July, but yes, his article in 2009, yes, that's  
4 the article I'm referencing.

5 Q Okay.

6 As you were gathering the data and then  
7 participating in the writing of this article that  
8 was published in July 2009, you said that there  
9 were things that you were learning that had an  
10 impact on your understanding of the risks, and  
11 that, I believe you said, entered into your  
12 evaluation of the Prolift; correct?

13 MR. COMBS: Object to form.

14 THE WITNESS: Correct to some  
15 extent. It was -- I knew those risks were  
16 present. You know, I knew these risks that  
17 we talk about in the article were present.  
18 The question is the prevalence or not of the  
19 problems became a little bit clearer when we  
20 had gone back and looked retrospectively at  
21 the data, because it was the combination of  
22 all four of us who were doing the surgery  
23 rather than just my own specific clinical  
24 experience with the patients.

25

1 BY MR. SLATER:

2 Q And what was it that you learned that  
3 was of significance to you in connection with this  
4 article that was published in July 2009 that had  
5 an impact on your evaluation or your analysis of  
6 the risk/benefit profile for the Prolift?

7 A There were two issues, I think. One was  
8 that the rate of post-operative stress  
9 incontinence ran, as the article says, around 25  
10 or so percent, and that that information was  
11 actually similar to what was being reported  
12 through the CARE trial for sacrocolpopexies and  
13 the likelihood of postoperative stress  
14 incontinence for sacrocolpopexies.

15 So looking at the two procedures, the  
16 concept that there was somewhat similar risks of  
17 post-operative stress incontinence in women  
18 post-op from a sacrocolpopexy versus a Prolift, my  
19 perception, actually prior to getting all of this  
20 data together, was that there was actually less  
21 likelihood of post-operative stress incontinence  
22 in the Prolift patients versus patients who had  
23 undergone sacrocolpopexy.

24 That was my sort of personal Gestalt  
25 when I had been doing these surgeries, but the

1 data suggest that it's probably relatively  
2 equivalent. So it would simply mean that, you  
3 know, I counseled -- I did not change per se how I  
4 counseled patients regarding the risk of post-op  
5 stress incontinence, because we talk about that  
6 with any prolapse surgery that we do.

7 The second component was the issue of  
8 the pain issue, and that there were a group of  
9 patients who were -- who we had more difficulty  
10 treating post-operative pain issues. We hadn't  
11 really looked at that in our sacrocolpopexy  
12 patients or any of the other kinds of prolapse  
13 patients we did. We hadn't really gone back and  
14 looked at specifically the number of patients who  
15 experienced post-operative pain issues and whether  
16 there was any kind of consistent pattern that we  
17 could pick up preoperatively that we could use in  
18 counseling, predicting, selecting patients, et  
19 cetera.

20 This was sort of the first time we went  
21 back and looked at those kind of issues, so it  
22 alerted me to that for Prolift. It also then  
23 alerted me to looking at that for other prolapse  
24 patients that were having sacrocolpopexies or  
25 colpectomies, et cetera. So it altered some of my

1 preoperative evaluation of patients regardless of  
2 which prolapse surgery I offered, and it altered a  
3 little bit my preoperative management of some of  
4 those patients.

5 A long answer, but hopefully that  
6 clarifies it.

7 Q Were the findings that you just  
8 described to me factors in your decision to stop  
9 using the Prolift?

10 A No.

11 Q Did you -- in the patients that you  
12 operated on up until the point when you stopped,  
13 did you modify your consent discussion in any way  
14 as a result of what you just told me about, the  
15 SUI rates and the pain issues and the difficulty  
16 treating pain?

17 A I did not modify the SUI counseling,  
18 because it was essentially -- you know, that was  
19 essentially similar rates we were quoting for  
20 patients from prolapse surgeries of 20 to  
21 40 percent based on CARE data and some of the  
22 other data in the literature. So it didn't really  
23 change, since the 25 percent fit into that area.

24 The issue of counseling the patients  
25 regarding post-op pain issues, it changed how I

1 counseled them based on the changes of my  
2 preoperative examination.

3           So if I had a patient with, you know,  
4 fibromyalgia, or I had a patient who gave me a  
5 history of underlying orthopedic issues, back  
6 problems, hip problems, knee problems, et cetera,  
7 patients who I felt were then potentially more at  
8 risk for having, you know, some pelvic muscle  
9 spasm or pelvic muscle problems even pre-surgery,  
10 I became much more aggressive in my preoperative  
11 assessment of that and screening them for  
12 biomechanical issues, screening them more  
13 intensively for pelvic muscle spasm preoperatively  
14 or any symptoms that might suggest that, and then  
15 counseling them that regardless of what procedure  
16 we do, Prolift or anything else, you need to be  
17 pretreated with physical therapy so that we can  
18 make your post-operative course a little bit  
19 easier for you.

20           If we don't and we just operate on you  
21 as is, that your post-operative course may be more  
22 difficult and that you may have more problems with  
23 pain issues, or you may need physical therapy.

24           Even if we did pretreat -- pre-diagnose  
25 it and pretreat it, we did have conversations with

1 patients that we could still see a flare-up or  
2 some recurrence of these symptoms postoperatively  
3 that may require additional treatment. Regardless  
4 of whether we did Prolift or anything else, we  
5 just had -- by co-coincidence, we picked Prolift  
6 as our initial procedure to look at.

7 Q Well, you had studied the Prolift as  
8 part of this -- rephrase.

9 In this article you studied the Prolift,  
10 so that was the data you had available to you was  
11 Prolift; correct?

12 A Well, yes, but at the same time as we're  
13 collecting this data and we're seeing this  
14 information, we are also then beginning to use  
15 that sort of across the board when we evaluate  
16 patients postoperatively for pain issues if they  
17 have had a sacrocolpopexy, or if they've had a  
18 colectomy.

19 I mean this particular article for us or  
20 for me in particular was really sentinel in  
21 changing how, how aggressively I evaluate and  
22 manage orthopedic, biomechanical pain conditions  
23 in the pre- and the post-op patient, regardless of  
24 the procedure I chose, even for, you know, even if  
25 I was doing just a TVT.

1           Q     Your study that you published in  
2     July 2009 showed that there are some women who  
3     develop pain following Prolift surgery that do not  
4     respond to the treatment and could be left with  
5     chronic pain; correct?

6           A     They had not responded to the treatment  
7     to date at the time of the article. I mean some  
8     of the patients we don't know, because they were  
9     lost to follow-up.

10          Q     During the time of the study, there were  
11     patients who did not respond to treatment, and  
12     their pain continued until the end of the study;  
13     correct?

14          A     Correct.

15          Q     Did you change your counseling in any  
16     way to start to counsel patients that the pain  
17     that could result from a Prolift procedure,  
18     despite treatment, could become chronic and  
19     untreatable?

20          A     I --

21          Q     That's a yes-or-no question. I really  
22     just need to know if that's something you  
23     counseled your patients about.

24                     MR. COMBS: Objection.

25                     THE WITNESS: I had, I had



1           previously counseled the patients about that,  
2           so no, I didn't change my counseling.

3       BY MR. SLATER:

4           Q     Did you always counsel your patients  
5           about that, or was there a point in time when you  
6           started to?

7           A     I always counseled.

8           Q     You actually pointed out in the article  
9           that you believed that some of the patients had  
10          pelvic pain due to mesh bunching and banding.

11                     I want to ask you about mesh banding.  
12          That is what Pam Wicker had; correct?

13                             MR. COMBS:   Object to form.

14                             THE WITNESS:   She had that at one  
15          point in her care, yes.

16       BY MR. SLATER:

17           Q     And you pointed out in the article that  
18           the banding can occur either due to the amount of  
19           tension left on the mesh during the procedure, on  
20           the actual arms, or it can happen if the mesh is,  
21           as you describe it, properly placed due to  
22           contraction with tissue ingrowth.

23                     It can happen for either reason;  
24          correct?

25           A     That is the hypothesis, yes.

1 Q And that's your, that's your current  
2 hypothesis and your current opinion; correct?

3 A Correct.

4 Q So the mesh banding in the arms of the  
5 Prolift in Pam Wicker, in your opinion, occurred  
6 either due to the amount of tension left on the  
7 arms at the conclusion of the procedure or due to  
8 mesh contraction with tissue ingrowth following  
9 the procedure.

10 You think those are the two likely  
11 causes; correct?

12 MR. COMBS: Object to form.

13 THE WITNESS: For the -- those are  
14 the two likely causes for the initial banding  
15 I think that was noted when Dr. Bercik took  
16 her back to the operating room on the second  
17 occasion. I'm not sure --

18 BY MR. SLATER:

19 Q Answer my question. That's all I was  
20 asking about.

21 A But there's also banding in discussions  
22 potentially that Raz is talking about, and so  
23 that's a separate issue, but if you're talking  
24 just Bercik's second operation, then yes, those  
25 would be the two possibilities.

1 Q Move to strike from "but" forward.

2 Dr. Raz clinically found what he  
3 reported as tension bands of mesh around the  
4 vagina; correct?

5 A He reported in his first examination  
6 that he felt a band, yes.

7 Q That would likely be due to contraction  
8 of the mesh due to tissue ingrowth; correct?

9 MR. COMBS: Object to form.

10 THE WITNESS: It is possible for  
11 that, but it's also possible because she's  
12 had the subsequent intervention from Bercik's  
13 second surgery, so it's hard to say which one  
14 of those were the biggest contributing factor  
15 going into what Raz saw.

16 BY MR. SLATER:

17 Q Do you believe it was a combination of  
18 something that happened when Dr. Bercik operated  
19 in February of '09 and contraction due to tissue  
20 ingrowth that led to that banding Dr. Raz found?

21 A I think that there is, yeah, reasonable  
22 possibility that both factors were probably  
23 involved.

24 Q What about Dr. Bercik's February 2009  
25 surgery would have contributed to that mesh

1 banding that Dr. Raz found?

2 A Well, there was, there was mesh banding  
3 in association with scarring and vaginal, you  
4 know, a vaginal band. So it wasn't just an eroded  
5 mesh band. It was a combination of the two. So  
6 it is conceivable that what Dr. Raz found was  
7 either from disruption of the Prolift mesh that  
8 occurred during Dr. Bercik's second surgery and  
9 potential retraction from the surgery he did the  
10 second time, whether there was simply tightening  
11 or scarring of that area, that vaginal -- that  
12 vaginal tissue mesh, if you want to use that as a  
13 combination, that band could have also been  
14 partially due to scar tissue that forms just from  
15 having had another procedure done.

16 Q And you think more likely than not, it  
17 was probably a combination of the two?

18 A Yes.

19 Q Plus, plus just contraction due to  
20 tissue ingrowth as well?

21 MR. COMBS: Object to form.

22 THE WITNESS: I thought that was  
23 what you were talking -- can you go back and  
24 repeat the question. I'm sorry.

25

1 BY MR. SLATER:

2 Q We're on the same page, so just to be  
3 clear, it's your opinion that it's more likely  
4 than not that that banding that Dr. Raz found was  
5 due to a combination of what occurred during the  
6 procedure Dr. Raz performed, as you described it,  
7 and contraction due to tissue ingrowth; correct?

8 MR. COMBS: Object to form.

9 THE WITNESS: You said Dr. Raz, so  
10 I think that that's not quite what the  
11 question is.

12 BY MR. SLATER:

13 Q Okay.

14 A My understanding --

15 Q I misstated the question. Let me reask  
16 it clean, just because otherwise the transcript  
17 won't be clean.

18 And it's your opinion that it's more  
19 likely than not that the banding Dr. Raz found was  
20 due to the surgery Dr. Bercik did, as you  
21 described it a moment ago, in combination with  
22 contraction due to tissue ingrowth; correct?

23 A Yes, with a small caveat.

24 That small caveat would be I don't know  
25 whether or not the, quote, tissue ingrowth or

1     contracture, whatever you're talking about,  
2     whether that was a new phenomenon that occurred  
3     between Dr. Bercik's second surgery and Dr. Raz's  
4     first surgery, or was it potentially there even at  
5     the first surgery to some extent and not  
6     addressed, or by operating and doing what he did  
7     at the second surgery, had he created a degree of  
8     vaginal distortion that then pulls on the area  
9     differently, and so the result is that combination  
10    mesh vaginal band.

11                 So that's the hard part. Once you've  
12    had the intervention of Dr. Bercik, it becomes  
13    more difficult to say it's only caused by one  
14    thing.

15                 Q     Whether it's one of those things or some  
16    combination of those factors you've listed, they  
17    would all be causally connected to the Prolift  
18    being in her body and then the treatment of the  
19    complication of the contraction and the tension  
20    band that Dr. Bercik treated in February; correct?

21                         MR. COMBS: Object to form.

22                         THE WITNESS: They would all be  
23    related to the fact that there's a Prolift  
24    there, yes.

25

1 BY MR. SLATER:

2 Q Okay.

3 You would agree the surgery Dr. Bercik  
4 performed was indicated; correct?

5 A Hang on just a second.

6 I -- based on his description of what he  
7 found, it is certainly one option for treating it.  
8 I probably would have considered a possible more  
9 conservative option first, with trying to use some  
10 physical therapy and see if you can improve the  
11 pliability of the tissue prior to going in to, you  
12 know, to cut or excise the mesh band.

13 I think it would be dependent on how  
14 tight it really was of the tightness. I mean  
15 that's a subjective statement, but certainly a  
16 very, very tight one that I didn't think was going  
17 to be amenable to any type of tissue mobilization  
18 or improvement of pliability by manual  
19 manipulation, then I would have potentially  
20 considered going in and reoperating on the  
21 patient.

22 Q Ultimately Dr. Bercik was -- rephrase.

23 Ultimately Dr. Bercik was exercising his  
24 medical judgment as a surgeon as to what he  
25 thought was the best way to treat this pain that

1 Mrs. Wicker was complaining of from the Prolift;  
2 correct?

3 MR. COMBS: Object.

4 THE WITNESS: Yes. That appears to  
5 be the case. He was exercising his best  
6 judgment.

7 BY MR. SLATER:

8 Q In fact, in your July 2009 article you  
9 talk about the fact that in two of the patients,  
10 you actually excised mesh for pain, "and in both  
11 cases we attempted to excise and release banding  
12 that was palpable on examination rather than  
13 remove the entire mesh."

14 And that's essentially what Dr. Bercik  
15 did; correct? He released the banding and removed  
16 contracted mesh; correct?

17 A Yes, that's correct.

18 Q You talked a few minutes ago about the  
19 fact that you were more focused on the literature  
20 from predating Mrs. Wicker's surgery and you  
21 weren't as concerned with literature post-dating  
22 it, and we talked about that a few minutes ago.

23 Do you remember that?

24 A When I was forming some of the opinions  
25 that were in my report initially about



1 decision-making process at that time, I mean  
2 certainly I'm looking at the literature post that  
3 to see whether it either confirms some suspicions  
4 or doesn't confirm suspicions or raises new issues  
5 or puts, you know, the old issues, you know, out  
6 of the picture.

7 Q If there were important issues with the  
8 Prolift safety -- rephrase.

9 If there were important safety issues  
10 with the Prolift that were discussed in literature  
11 after October 2008, but Ethicon internally knew  
12 those issues prior to the October of 2008 but  
13 didn't warn about them, you would be critical of  
14 that; right?

15 MR. COMBS: Object to form.

16 THE WITNESS: I mean I think it  
17 would depend. It would depend on what  
18 Ethicon knew regarding the safety data or, or  
19 not. I mean I could say other things, but  
20 you're just going to say strike it, so I'll  
21 say it would depend on whether, what Ethicon  
22 knew about the safety data and what level of  
23 risk the safety data indicated.

24 BY MR. SLATER:

25 Q Do you know whether or not Ethicon

1 Medical Affairs was learning about risks and  
2 adverse events with the Prolift after  
3 October 2008, or do you know as an alternative  
4 whether they claim to have known all the risks and  
5 adverse events from the very beginning?

6 Do you know one way or the other?

7 MR. COMBS: Object to form.

8 THE WITNESS: I don't know what  
9 they claim. I have sort of my opinion --

10 BY MR. SLATER:

11 Q The question, though.

12 A Yes. I don't know what they claimed.

13 Q Okay.

14 If Ethicon knew about a risk that had  
15 not been described publicly, and that risk, if it  
16 occurred to a woman, could cause very severe  
17 injury to her, you would agree that risk would  
18 need to be disclosed? And I'm talking about  
19 obviously with regard to the Prolift. You'd agree  
20 with that; right?

21 MR. COMBS: Object to form.

22 THE WITNESS: I think that, yes,  
23 depending upon the, the frequency of the  
24 risk. You know, if there's something that  
25 happens, you know, as one, once or twice, you

1 know, incidental report, a death, things like  
2 that, I mean you -- that's always a  
3 possibility with surgeries, but I think if it  
4 was something that was a repetitively present  
5 problem, that that information needs to be  
6 communicated whether it's by the company or  
7 whether it's by us in the literature.  
8 Sometimes we beat the companies.

9 BY MR. SLATER:

10 Q You found in your July 2009 study that  
11 3 percent of the women who had pelvic pain as a  
12 result of the Prolift, it could not be  
13 successfully treated through conservative  
14 measures, and you talked about the fact that this  
15 could be due to bunching or banding of the mesh,  
16 and that that was leading to contraction; correct?

17 MR. COMBS: Object to form.

18 BY MR. SLATER:

19 Q You talked about 3 percent of the women  
20 having that situation?

21 A We talked about 3 percent of the women  
22 having that situation, as we talked about before,  
23 by the end of the study.

24 Q And again, how long was that?

25 A We followed the patients -- I'd have to

1 pull out the article to see what the average  
2 length of follow-up was for the patients and what  
3 the standard deviation is. I don't remember off  
4 the top of my head, but it's probably going to be  
5 in the results.

6 Q It says on the front page "mean  
7 follow-up was eight months." Does that sound  
8 right?

9 A Yeah, that could be right, because it's  
10 going to be patients that were relatively recently  
11 treated or patients that were part of the earlier  
12 group, but it also should give you a standard  
13 deviation or a range, in parenthesis.

14 Q I'm just looking at the abstract. It  
15 doesn't say it. It just says "mean follow-up was  
16 eight months."

17 A Hang on two seconds. I actually -- I  
18 did bring it. I just have to find it.

19 Q You know, I'm actually not that  
20 concerned about the time period. My question  
21 really goes to something else.

22 A Okay.

23 Q Let me ask you this question.

24 If Ethicon knew that there were women  
25 who were going to have the Prolift put in their

1 body, and as much as 3 percent of women were going  
2 to have pain due to the Prolift that would not be  
3 able to be resolved with conservative therapy, and  
4 that that would relate to mesh bunching, mesh  
5 banding due to mesh contraction, if they knew of  
6 that, should they have warned about that from the  
7 point they became aware of it?

8 MR. COMBS: Object to form.

9 THE WITNESS: I think that they  
10 should warn about the risk of pelvic pain  
11 after the procedure, whether it's due to mesh  
12 bunching or banding or whatever the reason.  
13 I think if there is -- if that is a risk of  
14 the procedure, then it should be part of what  
15 is in the warning.

16 BY MR. SLATER:

17 Q Do you believe that if Ethicon knew that  
18 the pelvic pain some women would experience due to  
19 the Prolift would not be able to be safely and  
20 effectively treated, if the company actually knew  
21 that, that they should have warned doctors and  
22 patients as to that fact, that you may not only  
23 get pelvic pain, but it may not be treatable?

24 A The issue of having that as a specific  
25 statement in the literature, I mean I think that's

1 a hard thing to say, because whether you say that  
2 specifically or whether you say that the surgeon,  
3 more so maybe than the patient, that the surgeon  
4 needs to be aware of the risks and problems and be  
5 familiar with mesh and be familiar with treating  
6 patients with prolapse.

7 I mean a risk of persistent pain after a  
8 mesh procedure, whether it's a Prolift, a TVT,  
9 sacrocolpopexy, there is that risk, and that may  
10 not be resolvable, it may not be reversible in a  
11 patient, but that's in any of the patients that we  
12 use a mesh procedure.

13 So does -- is Ethicon's role to  
14 specifically spell that out as a statement versus  
15 to say physicians need to be aware of the risks  
16 associated with mesh surgery? I mean, in part,  
17 the people that are doing the surgery, and if  
18 indeed they have that experience in whatever,  
19 already know that that is an issue, that the  
20 chronic pain could happen after a Prolift and that  
21 it may not be treatable, I mean that's inherent in  
22 knowing about doing mesh surgery.

23 Q Do you know that the Prolift was  
24 marketed as a revolutionary new procedure?

25 A I'm not sure that the term

1 "revolutionary" per se was used. It may have been  
2 used, but it was certainly marketed as a new  
3 procedure and being able to address things in a  
4 different way than we had done before.

5 Q And therefore, it would be important to  
6 make sure that doctors are told the full scope of  
7 risks, especially those that could be more severe,  
8 so the doctor would not be misled into thinking,  
9 well, this is new. This is supposed to be so much  
10 better than everything else, I don't have to worry  
11 about these other issues I may have thought could  
12 exist with mesh, because they're not telling me  
13 it's a risk with this Prolift.

14 Isn't that a fair analysis?

15 MR. COMBS: Object to form.

16 THE WITNESS: No, because that  
17 would assume the physician is an idiot,  
18 because the problem is that there's no  
19 physician who's going to sit there and think,  
20 oh, well, I've been told by Ethicon this is  
21 revolutionary and it involves mesh, and it's  
22 going to eliminate any of the mesh problems  
23 that I know can exist from all these other  
24 procedures where we do mesh.

25 I mean you would have to be really

1       naive, not thinking medically, you know, to,  
2       to make that assumption, and I can't really  
3       see any experienced surgeon who was doing  
4       prolapse surgery, who was doing, you know,  
5       mesh -- with or without mesh, thinking that  
6       this procedure could, would eliminate the  
7       possibility of a chronic pain issue and that  
8       it would eliminate the possibility of  
9       long-term pain that we can't treat.

10               I just can't conceive of any  
11       surgeon thinking that, regardless of what --  
12       even if Ethicon told you that that was going  
13       to be the way it was going to be, I wouldn't  
14       believe it, because the bottom line is we  
15       already know from our other experiences that,  
16       that, that it's not necessarily the case.

17   BY MR. SLATER:

18       Q       Well, you're talking about what your  
19       reaction would be. Have you ever studied what  
20       other doctors' reaction would be or how they  
21       interpret warnings or information on labeling for  
22       a medical device? Have you ever studied that  
23       question?

24                       MR. COMBS: Object to form.

25                       THE WITNESS: I have not studied



1 the question.

2 BY MR. SLATER:

3 Q If Ethicon knew from the very beginning  
4 that the arms could become contracted and become  
5 what we've been discussing as tension bands,  
6 requiring surgery to get into those deep areas of  
7 the pelvis to remove some of that mesh, but that  
8 that might not resolve the pain being caused by  
9 this contracting mesh, should that have  
10 specifically been warned about, that phenomenon  
11 specific to the Prolift?

12 MR. COMBS: Object to form.

13 THE WITNESS: Well, it's not a  
14 phenomenon specific to the Prolift. So I  
15 mean it's a phenomenon --

16 BY MR. SLATER:

17 Q The arms, the arms exist with the  
18 Prolift -- I'm talking about the Prolift arms.

19 A I understand that, but TVT has arms, TOT  
20 has arms. Those all can -- you know, those are  
21 all mesh surgeries that have arms going into  
22 tissue.

23 So I'm just trying to --

24 Q My question is simple. Here is my  
25 question.

1                   Should that have been warned about if  
2   Ethicon knew it at launch? Simple question. Yes  
3   or no?

4                   MR. COMBS: Object to form.

5                   THE WITNESS: Does that particular  
6   statement need to be placed in the warning?  
7   I would not think that it does, because I  
8   think it's already covered by the statements  
9   previously, which you have to have experience  
10   and knowledge base with prolapse surgery and  
11   meshes.

12   BY MR. SLATER:

13               Q     You think the warning said you need to  
14   have experience with --

15               A     If you --

16               Q     -- prolapse surgery and meshes?

17               A     Yeah.

18                   Sorry, sorry.

19               Q     Okay.

20               A     I think that --

21               Q     -- it says that --

22               A     I think that if you are an experienced  
23   surgeon use, with the use --

24               Q     Doctor, there's no question.

25               A     -- of materials --

1           Q     You're not answering a question right  
2     now.

3           A     Okay.

4           Q     You're not answering a question.  
5                   It can be difficult, if not impossible,  
6     to remove contracted mesh from some women  
7     following Prolift surgery; correct?

8           A     It can be very difficult. I'm not sure  
9     I could go, you know, go to the extent of saying  
10    impossible, but certainly it could be difficult  
11    and could maybe be conceivably impossible to take  
12    every bit out.

13          Q     If Ethicon knew that from the beginning,  
14    should that have been warned about; yes or no?

15                   MR. COMBS: Object to form.

16                   THE WITNESS: I don't think it  
17    needs to be a separate specific warning, no.

18    BY MR. SLATER:

19          Q     If Ethicon knew from the date of launch  
20    of the Prolift that in some women the surgeon  
21    would not be able to safely and effectively remove  
22    mesh where necessary to treat complications, if  
23    that was known, should that have been warned  
24    about?

25          A     I don't think it needs to be

1 specifically stated as such.

2 Q And your -- and that opinion is based on  
3 the fact that you just think doctors would just  
4 figure that out all by themselves?

5 MR. COMBS: Object to form.

6 THE WITNESS: Doctors who do --  
7 yes, doctors who do mesh surgery.

8 BY MR. SLATER:

9 Q -- stop you for a second.

10 A I'm sorry. You, you cut out.

11 Q We're talking --

12 A You cut out.

13 Q Let me stop you for a second.

14 MR. COMBS: Well, wait, wait a  
15 second. We're, we're not --

16 MR. SLATER: No, Phil, I'm  
17 talking --

18 MR. COMBS: No.

19 MR. SLATER: -- so you don't  
20 interrupt me.

21 MR. COMBS: Well, no. We're not  
22 going to both speak at the same time.

23 MR. SLATER: We're almost at lunch.

24 MR. COMBS: She did not get to  
25 finish her answer.

1 MR. SLATER: Well, this is the  
2 problem. I asked a yes-or-no question, and I  
3 have been very polite and let Dr. Horbach  
4 talk at length today, but now we're going to  
5 finish the deposition today. We need to go  
6 to the part of the deposition where when I  
7 ask you a yes-or-no question, I get a yes or  
8 a no or you say you can't answer with a yes  
9 or no.

10 MR. COMBS: But you're not going  
11 to --

12 MR. SLATER: And that's the part of  
13 the deposition we -- I'm talking, so please  
14 don't talk over me. There is no way for the  
15 court reporter to record two people at the  
16 same time.

17 BY MR. SLATER:

18 Q So that was a simple yes-or-no question,  
19 and I know you want to get done today, and so do  
20 I, so I'm going to ask you to just answer the  
21 questions with a simple yes or no. I don't want  
22 explanations unless I ask for them.

23 MR. COMBS: Are you finished? Are  
24 you finished, Mr. Slater?

25 MR. SLATER: Yeah, I'm finished,

1 Phillip.

2 MR. COMBS: Now, we're not going to  
3 interrupt Dr. Horbach in the middle of her  
4 answer with you berating her for what you  
5 believe was an inappropriate answer.

6 Now, if you don't like her answer,  
7 you can object, but you're not going to  
8 interrupt her, and you're not going to berate  
9 her about it.

10 MR. SLATER: What do you want to  
11 do?

12 MR. COMBS: You can ask her  
13 questions and she can answer them, but you're  
14 not going to interrupt her, and you're not  
15 going to be -- you're not going to make  
16 inappropriate comments about it. That's --

17 MR. SLATER: Thank you for your  
18 guidance.

19 BY MR. SLATER:

20 Q Dr. Horbach, is the answer to my  
21 question yes, or is the question [sic] no?

22 MR. COMBS: Object.

23 THE WITNESS: Could you read -- or  
24 could the court reporter read the question  
25 back for me?

1 MR. SLATER: Of course.

2 (Whereupon, reporter reads  
3 requested material.)

4 THE WITNESS: Yes.

5 BY MR. SLATER:

6 Q -- in terms of what doctors knew --

7 A I'm sorry. You cut out on the beginning  
8 of that.

9 Q Sure. I'll ask again.

10 Have you ever studied in any way what  
11 doctors knew aside from the warnings that were  
12 given by Ethicon with regard to the particular  
13 risks of not being able to safely or effectively  
14 treat Prolift-related mesh complications? Have  
15 you ever looked at that?

16 A I have not studied it, no.

17 Q I want to come back to my question about  
18 the TVM group literature. There are several  
19 articles that I'm familiar with that are not on  
20 your list of materials reviewed. Therefore --  
21 well, let me ask it differently.

22 Are you familiar with an article that  
23 was authored by Dr. Velimir and Dr. Jackatan  
24 regarding a review of mesh with ultrasound?

25 A Yes.

1 Q Did you see the level of the rates of  
2 contraction that they found on that study?

3 A Yes.

4 Q Those rates were alarming, weren't they?

5 MR. COMBS: Object to form.

6 THE WITNESS: I think that's a  
7 subjective statement. There were various  
8 rates. They were what they were.

9 BY MR. SLATER:

10 Q You would agree -- you would agree  
11 they're very concerning; right?

12 A They were what they were. You have the  
13 make the -- the individual has to make the  
14 subjective conclusion about it.

15 Q But you're the individual I'm asking  
16 now, and that study showed over 80 percent of the  
17 women had moderate to severe retraction of Prolift  
18 mesh.

19 That is a concerning finding; correct?

20 MR. COMBS: Object to form.

21 THE WITNESS: It is a concerning  
22 finding in the group of patients that they  
23 selected.

24 BY MR. SLATER:

25 Q You did not look at the ultrasounds



1 performed by Dr. Raz, did you?

2 A Yes.

3 Q You did look at them?

4 A Yes.

5 Q I didn't see any opinions in your report  
6 about those ultrasounds; correct?

7 A I did not reference it in either report,  
8 no, but I mean it's not something -- it is  
9 something that I would potentially give an opinion  
10 about if asked.

11 Q You didn't mention it in your report;  
12 right? You didn't give any opinions about the  
13 ultrasounds at all in your report; right?

14 A No, I did not state that.

15 Q Have you ever in your medical practice  
16 used ultrasounds to locate mesh?

17 A Yes.

18 Q In a woman's body?

19 A Yes.

20 Q How often? How many times?

21 A A couple times. Not a huge number, but  
22 several.

23 Q Less than five?

24 A I don't know.

25 Q Did you find that to be a useful tool to

1 help to locate mesh?

2 A In one particular patient it was  
3 helpful, because the mesh was about one millimeter  
4 by two millimeters, and I'm not even sure it  
5 really was mesh, but in the other patients I don't  
6 think it really was specifically helpful, because  
7 the clinical impression helped me know where I was  
8 looking for the mesh anyway.

9 Q Was there a particular protocol used  
10 when the ultrasounds were performed on those  
11 patients that were your patients?

12 A A particular protocol in terms of what  
13 the radiologist did?

14 Q In terms of how he -- was there --  
15 rephrase.

16 Was there a particular protocol used in  
17 terms of how the ultrasounds were performed with  
18 your patients?

19 A It was -- I can't answer that question.  
20 I don't know, because it was done by radiology.

21 Q Okay.

22 Did you read that Dr. Raz actually  
23 interacted with the radiologist at UCLA Medical  
24 Center, and together they developed a protocol to  
25 image mesh on ultrasound?

1           A     I know that he has a protocol that he  
2     does, and I know that I spoke to my radiologist  
3     about the same issues in trying to discuss what is  
4     the best method -- what is the best method to  
5     answer the question that I'm looking for, and so  
6     if I talk to a radiologist and I say this is what  
7     I'm concerned about, this is what I'm looking at,  
8     ideally they use their expertise to be able to --  
9     use their expertise to be able to answer the  
10    question. So I'm not going to tell them per se  
11    how to do their protocol any more than they'll  
12    tell me.

13           Q     Move to strike.

14                     I don't -- Doctor, with all due respect,  
15    I don't know why you're telling me that. I didn't  
16    ask any questions about that. It was a very  
17    simple question.

18                     Here is my question.

19                     Did you read that Dr. Raz worked  
20    together with a radiologist at UCLA Medical Center  
21    to establish a protocol to specifically use  
22    ultrasound to image mesh?

23           A     I don't recall reading that he  
24    specifically worked with the radiologist versus he  
25    doing it himself.

1           Q     Do you dispute that Dr. Raz imaged mesh  
2     with the ultrasound as he testified to?

3                     MR. COMBS: Object to form.

4                     THE WITNESS: I think that the  
5     photographs that I saw of the ultrasounds do  
6     indicate mesh.

7     BY MR. SLATER:

8           Q     Did you actually look at the actual  
9     ultrasounds themselves, the actual electronic  
10    films?

11          A     No. I looked at pictures of it rather  
12    than the film itself.

13                    MR. SLATER: Why don't we do this.  
14     It's 1:00. We said 45 minutes, so why don't  
15     we break for lunch until 1:30 and resume.  
16     Does that sound good?

17                    MR. COMBS: Yeah, we'll try. It  
18     may take a little bit longer than 1:30, but  
19     we'll try. We'll definitely try to keep this  
20     break as short as we can.

21                    MR. SLATER: All right. Let's try  
22     to shoot for 1:30 if you want to get out of  
23     there.

24                    (Discussion was held off the  
25     record.)

1 THE VIDEOGRAPHER: Off the record  
2 at 12:56.

3 (Whereupon, the lunch recess was  
4 taken.)

5 THE VIDEOGRAPHER: Our time now is  
6 1:43. On record.

7 BY MR. SLATER:

8 Q Okay.

9 Doctor, we've now gone through and  
10 discussed Exhibits 2 -- and 5, which are the three  
11 reports that you authored in this case; correct?

12 (Discussion was held off the  
13 record.)

14 BY MR. SLATER:

15 Q Doctor, we've now gone through the three  
16 reports you've written in this case, which we've  
17 marked as Exhibits 2, 3 and 5; correct?

18 A Correct.

19 Q And when you wrote those reports you  
20 understood that you needed to express each of the  
21 opinions that you formed in those reports;  
22 correct?

23 A Yes.

24 Q And you did, in fact -- rephrase.

25 And those reports contain each of the

1 opinions you formed in this litigation; correct?

2 A Yes.

3 Q When you wrote those reports, did you  
4 write them carefully in the sense that you picked  
5 your words carefully and tried to express as  
6 clearly as possible what you intended to state?

7 A Yes.

8 Q For example, if you found, in your  
9 opinion, that something was likely or probable,  
10 you would say that; correct?

11 A I would assume that if -- if it was  
12 likely or probable by my definition of likely or  
13 probable, then I would use that word.

14 Q I -- in my -- rephrase.

15 I deposed you previously in August of  
16 this year, August of 2013.

17 Do you recall that?

18 A Yes.

19 Q What I'd like to do now is see if I can  
20 avoid going over old ground, so that's why I'm  
21 going to ask you the following question.

22 In that deposition, when I questioned  
23 you about your background, when I questioned you  
24 about your experience, when I questioned you about  
25 your opinions that were separate and apart from

1 specific questions about the specific patient in  
2 that case, if I were to ask you those same  
3 questions today, could I expect to receive the  
4 same answers?

5 MR. COMBS: Object to form.

6 THE WITNESS: I would expect so. I  
7 mean I can't say to absolute, because I'd  
8 have to go back and read each of those  
9 questions, but I would expect I would say the  
10 same answers.

11 BY MR. SLATER:

12 Q Did you review that deposition  
13 transcript?

14 A I read part of the deposition  
15 transcript, skimmed more the other part of it.

16 Q When you say you read part but skimmed  
17 the other, did you skim the part that had to do  
18 with that patient that was at issue in that case  
19 but read the balance?

20 A I think the majority of what I did  
21 reading-wise, I think, was in the earlier part of  
22 the deposition, and there were a number of  
23 discussions relative to what I thought about  
24 Ethicon's knowledge and Ethicon's  
25 responsibilities, et cetera. That part I did

1 read.

2 Q And with regard to those parts, was  
3 there anything you saw where you said, oh, that's  
4 wrong, or anything that you would say now you'd  
5 give a different answer?

6 A I don't believe so.

7 Q Okay.

8 A I'm sorry. We had talked about the  
9 issue, the one correction about when I stopped  
10 doing TVTs -- or not TVTs. Sorry. Prolifts that  
11 I corrected from instead of being 2011-ish, that  
12 it was 2009, and --

13 Q Right.

14 A -- I'm trying to think if there were  
15 anything -- I think that was the major issue. It  
16 turns out that I -- oh, the other correction was  
17 you had asked me how long I had spent on looking  
18 at just Pamela's records and stuff. I guess --  
19 well, maybe it was the -- I think I had perhaps  
20 underestimated the number of hours, but I think --  
21 the rest of it I think is pretty -- I didn't, I  
22 didn't mark anything else that was to be  
23 corrected.

24 Q Okay.

25 You do not practice orthopedics, do you?



1           A     No.

2           Q     You do not hold yourself out as an  
3     expert in the field of orthopedics, do you?

4           A     No.

5           Q     When Pam Wicker went to Dr. Bercik,  
6     there were several alternative treatments and  
7     treatment strategies that would have been  
8     reasonable; correct?

9           A     There were other treatment strategies  
10    besides the surgery, yes.

11          Q     And the reason -- the reasonable  
12    alternatives for Pam Wicker would have included,  
13    for example, doing nothing and just watching and  
14    waiting and seeing how she does going forward;  
15    correct?

16          A     Yes, a little bit, with the comment  
17    about relative to the pain issues she was  
18    experiencing. From the bulge itself, if you only  
19    look at the anatomy, yes, she could have gone  
20    ahead and just observed it.

21          Q     One option would have been for  
22    Mrs. Wicker to do pelvic floor strengthening  
23    exercises, not have surgery and see how she does  
24    going forward? That would have been one  
25    reasonable option; correct?

1           A     I would agree with all of that, other,  
2     other than perhaps the pelvic floor strengthening  
3     exercises. That's usually used more for  
4     incontinence patients than for prolapse patients.

5           Q     One option for Pam Wicker would have  
6     been to have a suture repair without mesh;  
7     correct?

8           A     Correct. Transvaginal suture repair  
9     without mesh, yes.

10          Q     -- option for Pam Wicker would have been  
11     to have abdominal sacrocolpopexy, whether open or  
12     laparoscopic; correct?

13          A     Yes, with perhaps some vaginal work done  
14     simultaneously. It would depend upon how the  
15     anatomy sort of ended up being at the end of the  
16     apical lift.

17          Q     And so each of those alternatives we  
18     just went through would have been reasonable  
19     alternatives to be selected; correct?

20          A     They are options that she could have  
21     considered, yes.

22          Q     Can you tell me to a reasonable degree  
23     of medical probability what would have happened if  
24     Pam Wicker had chosen one of those other options?

25          A     In terms of what?

1           Q     What happened within her pelvis, in  
2     terms of whether or not she would have had pain.  
3     What, if any, complications, whether or not she  
4     would have felt pain. Are you able to tell me  
5     what would have happened if she had taken another  
6     course?

7                     MR. COMBS: Object to form.

8                     THE WITNESS: I can give you my  
9     clinical opinion regarding what I think would  
10    happen in her case regarding a number of the  
11    different issues with the different  
12    approaches surgically, based to some extent  
13    on her clinical situation and based on what  
14    the literature says over all of the data,  
15    failures, success, et cetera.

16    BY MR. SLATER:

17           Q     Well, I want to ask you in the case of  
18    Pam Wicker, based on her own condition at the time  
19    that she went in to Dr. Bercik on October 20,  
20    2008, if she had had a suture repair or had no  
21    treatment as of that time or one of these other  
22    alternatives, are you able to tell me whether or  
23    not she would have had to have further surgery?  
24    Is there any way to know that?

25           A     I think that if she had had a

1 transvaginal suture repair without mesh, that  
2 there is probably -- there is a reasonable  
3 likelihood she would have had a recurrence of her  
4 prolapse and would have potentially faced another  
5 surgery.

6 Q What do you base that on?

7 A My, my knowledge of the literature as  
8 well as my experience over 25 years of doing these  
9 types of surgeries.

10 Q Are you saying that there would have  
11 been a statistical possibility of that occurring?

12 A Yes.

13 Q But you can't say to a reasonable degree  
14 of medical probability whether or not it would  
15 have occurred. You can just say statistically  
16 it's a possibility; correct?

17 A I think that in her case that it may be  
18 a little bit higher possibility than in other  
19 people, just based on her level of activity and  
20 her, the demands that she would be placing on her  
21 pelvic area and support tissues in the  
22 post-operative time.

23 So I think if I were to say would she be  
24 on the lower end of the recurrence rate or on the  
25 higher end of the recurrence rate, I think that

1 based on her age and the physical activity, that  
2 she would probably be on the higher end of the  
3 recurrence rate.

4 Q In terms of it being a statistical  
5 possibility?

6 A In terms of her experiencing a  
7 recurrence. I'm not sure what you mean about  
8 "statistical possibility."

9 Q All you can say is based on the  
10 literature and what you're looking at, that on a  
11 statistical basis there's a possibility that that  
12 would have needed to be done?

13 Rephrase.

14 You're saying that statistically it's  
15 possible she would have had a recurrence. You  
16 can't say that she would have had one or wouldn't  
17 have had one, because that's speculation, isn't  
18 it?

19 A It is, it is -- it is a -- it is a, an  
20 opinion based upon not just the literature and  
21 numbers, et cetera. It's based on clinically  
22 practicing and doing those operations for 25 years  
23 and seeing what the outcome is in patients who  
24 have those surgeries and watching them  
25 postoperatively.

1                   So I think that from, it's not just a  
2     purely statistical theoretic issue. I think those  
3     statistics have a basis, and they have a clinical  
4     basis, and in this particular patient, I think  
5     there is a clinical basis to say that she would  
6     have had a reasonable possibility of needing a  
7     subsequent surgery for prolapse if she had simply  
8     a transvaginal suture repair.

9                   Q     If Pam Wicker had not had a Prolift put  
10    in her body and had not had mesh put in, she would  
11    not have had mesh contraction; correct?

12                  A     Well, assuming she didn't have one of  
13    the alternative procedures done that involved  
14    mesh, but if she had only a native tissue  
15    procedure, then no, she wouldn't have had mesh in  
16    her body.

17                  Q     Okay. Move to strike.

18                         If Pam Wicker had not had mesh put into  
19    her body as part of the procedure, she would not  
20    have had a risk for mesh contraction; correct?

21                  A     The way you phrased it, I can't answer  
22    it. That's why I was trying to rephrase it in the  
23    way I did.

24                  Q     -- if she --

25                  A     I'm sorry. We lost you.

1           Q     If she did not have mesh put in her  
2     body, there would be no risk of mesh contraction;  
3     correct?

4           A     If she had no mesh put in under any  
5     circumstances in any type of alternative surgery,  
6     you're correct, she would not have had the risk of  
7     mesh contraction.

8           Q     And if Mrs. Wicker had not had mesh put  
9     into her body, she would not have had risk of mesh  
10    erosion; correct?

11          A     Correct.

12          Q     If Pam Wicker had not had mesh put into  
13    her body, she would not have needed operations to  
14    revise or remove contracted mesh or eroded mesh;  
15    correct?

16                   MR. COMBS:   Object to form.

17                   THE WITNESS:   The eroded mesh, I  
18                   would say yes.   Contracted mesh, hard to say.

19   BY MR. SLATER:

20          Q     Well, if she had no mesh in her body,  
21    how could she have surgery to remove her  
22    contracted mesh?

23          A     Sorry.   I sort of misinterpreted the  
24    question.

25                   So if she had no mesh in her body, she

1       couldn't have had surgery for contracted mesh.

2       You're correct.

3                       MR. SLATER:   What I'd like to do  
4       now is go to folder 20.   If you could,  
5       Stephanie, I want to mark that as the next  
6       exhibit.   The records in folder 20.

7                       (Exhibits 6 through 13 were marked  
8       for identification.)

9       BY MR. SLATER:

10       Q       Doctor, we've marked as Exhibit 13 the  
11       records that we got from Dr. Bercik.

12                    Have you seen those records?

13       A       I'm looking through them to see whether  
14       I've seen this -- I've seen what I presume are  
15       these records.

16       Q       You're confirming you have seen them;  
17       correct?

18       A       I'm looking through to confirm that.

19                    I believe I've seen all these records  
20       other than the billing statements.

21       Q       I don't expect to ask you about those,  
22       so we should be okay.

23                    Okay.

24                    First of all, when Pam Wicker came to  
25       Dr. Bercik, she was 58 years old; correct?



1           A     Correct.

2           Q     At that point she was a 50-year-old --  
3     rephrase.

4                     At that point Pam Wicker was a  
5     58-year-old, physically active and sexually active  
6     woman leading a fulfilling life; correct?

7                     MR. COMBS: Object to form.

8                     THE WITNESS: Based on -- you're  
9     asking me that based on this record in front  
10    of me?

11    BY MR. SLATER:

12           Q     Based on what you know.

13           A     Based on what I know, she was physically  
14     active and sexually active. I can't make any  
15     conclusion about whether she viewed that as a  
16     fulfilling life or not.

17           Q     Okay.

18                     When Pam Wicker came to Dr. Bercik, she  
19     was a young woman of 58 years old, she was  
20     sexually active and physically active?

21           A     Correct. Very young.

22           Q     Now, it's indicated that she had only  
23     felt this bulge very recently; right?

24           A     For two weeks.

25           Q     There's an indication of mild to

1 moderate pelvis pain, from your review of all the  
2 materials, is it your understanding that there was  
3 actual pain or that there was more pressure or  
4 discomfort from the bulge?

5 A Pain is referred to in, you know,  
6 several situations, based on this history, based  
7 on the deposition of her friend. My -- in my  
8 questioning of her during my IME, she doesn't  
9 necessarily describe it as much as pain.

10 So there's some saying pain yes and some  
11 saying no.

12 Q Putting all the information you have  
13 together, am I correct that as opposed to  
14 describing her sensation as pain, it would  
15 probably be more accurate to describe it as  
16 pressure and discomfort from the bulge?

17 MR. COMBS: Object to form.

18 THE WITNESS: I can't make that  
19 presumption. Patients can have pressure.

20 Patients can have no symptoms. Patients can  
21 have pain.

22 BY MR. SLATER:

23 Q So you can't say one way or the other  
24 here?

25 A I think that it's certainly conceivable

1 that she had pain as part of her presenting  
2 complaint. It's also conceivable not.

3 Q At the bottom of this front page, it  
4 states that she's sexually active and that she has  
5 "dyspareunia."

6 Do you see that?

7 A I see that.

8 Q If you flip to the next page, actually  
9 two pages later, in the GYN history at the top of  
10 page 3 it says that she denies various things,  
11 including denying pain with intercourse.

12 Do you see that?

13 MR. COMBS: Object to form.

14 THE WITNESS: Yes.

15 BY MR. SLATER:

16 Q So there's an inconsistency in the  
17 record as to whether or not Pam told Dr. Bercik  
18 she had dyspareunia or pain with intercourse at  
19 that first visit; correct?

20 A There's an inconsistency in the record.

21 Q And did you see Dr. Bercik's deposition  
22 testimony where he said he didn't know which was  
23 correct?

24 A Yes.

25 Q Did you see Pam Wicker's deposition

1 testimony where she said she did not have pain  
2 with intercourse or dyspareunia at that time?

3 A Yes.

4 Q Based on that information, did you draw  
5 an assumption one way or the other as to whether  
6 or not Pam Wicker had pain with intercourse?

7 A Initially based on those two pieces of  
8 information, it was difficult to conclude. Her  
9 friend in her deposition is quite -- stresses  
10 quite a bit that she was told by Ms. Wicker that  
11 she was having significant pain, including pain  
12 with intercourse.

13 Q Did you have an understanding as to  
14 whether or not her friend Jane Wallace was talking  
15 about before the Prolift surgery or after?

16 A It was before the Prolift surgery.

17 Q That was your understanding?

18 A Yeah, she said that's part of the reason  
19 that she had gone ahead and had the surgery.

20 Q There's clearly a conflict between the  
21 testimony of Pam Wicker and her friend Jane  
22 Wallace as well as right within the record of  
23 Dr. Bercik as to whether or not Pam had pain with  
24 intercourse before her Prolift surgery; correct?

25 A Yes.

1           Q     Do you feel comfortable drawing an  
2     assumption as to whether or not she was having  
3     painful intercourse, or is that something where  
4     you say I just don't know, there's no way to know?

5           A     If you assume that her comment is that  
6     she was having mild to moderate pelvic pain as  
7     part of her presenting symptoms, I would draw the  
8     conclusion that she also was having dyspareunia.

9           Q     And if you draw the conclusion that she  
10    was not feeling pain but was feeling discomfort  
11    and pressure, would that change your assumption?

12          A     It's possible that it would change it.

13          Q     Whether -- well, rephrase.

14                If we assume that Pam Wicker was having  
15    either pain or discomfort with sexual relations,  
16    that began two weeks before this visit of July 22,  
17    2008, when she noticed the bulge; correct?

18          A     That appears to be the timing, yes.

19          Q     And one of the -- rephrase.

20                One of the purposes of the Prolift is to  
21    resupport the bladder such that there's no longer  
22    a bulge and presumably no longer discomfort or  
23    pain with intercourse as a result of the bulge;  
24    correct?

25          A     That is one of the goals of the

1 procedure.

2 Q Now, during the exam -- rephrase.

3 During the exam, Dr. Bercik performed an  
4 examination of Mrs. Wicker's vagina both  
5 externally and internally; correct?

6 A Yes.

7 Q He rated her prolapse and did a POP-Q  
8 exam; correct?

9 A Yes.

10 Q He did not note finding any spasmodic  
11 muscles within the vagina, did he?

12 A He didn't note one way or the other, so  
13 it's not a pertinent negative or -- I mean it's  
14 not a, it's not a pertinent negative or a  
15 pertinent positive noted. Can't say one way or  
16 the other.

17 Q -- position whether he examined for  
18 signs of pelvic muscle spasm?

19 MR. COMBS: Yeah, Adam, you cut  
20 out --

21 THE WITNESS: That first part.

22 MR. COMBS: -- on half of the  
23 question.

24 MR. SLATER: Okay. I'll reask it.

25

1 BY MR. SLATER:

2 Q Was Dr. Bercik asked in his deposition  
3 whether or not his examination included feeling  
4 for pelvic floor muscle spasm?

5 A I don't recall that part of the  
6 deposition.

7 Q In forming your opinions, did you assume  
8 that Dr. Bercik did not examine for pelvic floor  
9 muscle spasm?

10 A I don't think I necessarily used that  
11 fact as a significant part of my opinion.

12 Q Being that Pam Wicker had pelvic  
13 floor --

14 A I'm sorry?

15 Q -- muscle spasm --

16 A I'm sorry.

17 Q I'm sorry. Sure.

18 Did you assume one way or the other  
19 whether or not Pam Wicker had pelvic floor myalgia  
20 or muscle spasm at the time that she went to see  
21 Dr. Bercik before she had the Prolift?

22 A I didn't assume --

23 Q Did you assume one way or the other?

24 A No.

25 Q Okay.

1                   Was it of any significance to you in  
2     forming your opinions whether or not she had  
3     pelvic floor muscle spasm or myalgia before the  
4     Prolift surgery?

5           A       Would it be of significance to me?  
6     Yeah.

7           Q       -- your opinions.

8           A       Yes. I understand, but I -- based on  
9     the information here, I formed my opinion that  
10    there was not conclusive evidence of pelvic muscle  
11    spasm indicated on the exam.

12                   Certainly it's not addressed per se one  
13    way or the other, so one would assume that he  
14    would have said positive if it was positive, but I  
15    took the approach that he had evaluated it and  
16    that it was not present on exam, and that is the  
17    basis for forming my opinion.

18          Q       So in forming your opinions in this  
19    case, you assumed that Pam Wicker did not have  
20    pelvic floor myalgia or muscle spasm before the  
21    Prolift surgery; correct?

22          A       There wasn't -- yeah. No. I mean there  
23    wasn't conclusive evidence that she did. I mean  
24    there's certainly a possibility she could have,  
25    but there wasn't conclusive evidence that she did.



1           Q     You, in drawing your opinions, assumed  
2     that she did not have pelvic floor myalgia before  
3     the Prolift surgery? That's the assumption you  
4     formed and then drew your opinions based on that;  
5     correct?

6           A     Yes, I believe that's probably correct.

7           Q     And just to be complete, it was your  
8     assumption that -- well, I'm going to withdraw  
9     that.

10                     Let's go to folder 5.

11                     (Exhibit 14 was marked for  
12                     identification.)

13     BY MR. SLATER:

14           Q     What we've marked as Exhibit 14 is the  
15     preoperative exam before the surgery from  
16     October 6, 2008.

17                     Do you see that?

18           A     Yeah, I'm just looking through.

19                     The, the handwritten portion of this I  
20     had not previously seen, the handwritten portion  
21     of the note. The rest of it, yeah, I think I had  
22     seen previously.

23           Q     Okay.

24                     I want to just draw your attention to  
25     the beginning of this document from this exam by

1 Dr. Klein where it says "Past Medical History."

2 Do you see that?

3 A Yes.

4 Q It indicates "she feels well, was having  
5 symptoms of vaginal prolapse, better now, no  
6 urinary symptoms."

7 Do you see that?

8 A Yes.

9 Q So that's what Pam Wicker reported to  
10 Dr. Klein two weeks before she was going to be  
11 operated on by Dr. Bercik; correct?

12 A Yes.

13 Q Did you see in Pam Wicker's deposition  
14 where she said that before Dr. Bercik operated,  
15 that she was still fully sexually active with her  
16 husband and was not feeling pain with intercourse?

17 A I don't remember that specific  
18 statement, but . . .

19 Q Okay.

20 Turn forward a couple pages to the  
21 operative report of October 20, 2008. It's in  
22 Exhibit 13, Dr. Bercik's records.

23 And do you see there's a preoperative  
24 diagnosis in his operative report?

25 A Yes.

1 Q One of the things listed is interstitial  
2 cystitis.

3 Do you see that?

4 A Yes.

5 Q Dr. Bercik did not diagnose interstitial  
6 cystitis. He was just placing that there, because  
7 that was part of the history given to him by  
8 Mrs. Wicker; correct?

9 A I assume that's why he placed it.

10 Q And you saw Dr. Moldwin's deposition in  
11 his records where he indicated he did not diagnose  
12 interstitial cystitis; he just documented the past  
13 diagnosis that had been brought to him by Pam  
14 Wicker as well.

15 Did you see that?

16 A Yes.

17 MR. COMBS: Object to form.

18 BY MR. SLATER:

19 Q And I read your report and didn't see  
20 any opinion on this, but I just want to be clear.  
21 You're not offering an opinion that Pam Wicker was  
22 suffering from active interstitial cystitis when  
23 the Prolift surgery was done, are you?

24 A No, I'm not offering. In fact, I don't  
25 think she was when the Prolift surgery was done.

1           Q     -- offer the opinion that she's  
2     had interstitial cystitis since the Prolift  
3     surgery; correct?

4                     MR. COMBS:   You cut out.

5                     THE WITNESS:   You cut out on that.

6     BY MR. SLATER:

7           Q     Trailed off again?   Okay.

8                     And I'm correct that you haven't joined  
9     the opinion that she's had interstitial cystitis  
10    since the Prolift surgery; correct?

11          A     I don't have -- I have not drawn that  
12    conclusion.   I don't really have evidence to  
13    suggest that diagnosis.   I don't have any strong  
14    evidence to suggest that diagnosis.

15          Q     Okay.

16                     The preoperative diagnosis that's listed  
17    there does not list dyspareunia; correct?

18          A     Correct.

19          Q     It does not list vaginal stricture;  
20    correct?

21          A     Correct.

22          Q     It does not list vaginal pain of any  
23    sort; correct?

24          A     Correct.

25          Q     Let's turn forward now to the

1 January 29, 2009 office visit. It's got a 66 in  
2 the bottom right corner in the Bates numbers.

3 Do you have that record?

4 A Yes, I do.

5 Q On January 29, 2009, Mrs. Wicker went to  
6 Dr. Bercik and advised him that she was having  
7 dyspareunia especially on the left side; correct?

8 A Yes.

9 Q Dr. Bercik performed an exam and found a  
10 band on the left side three centimeters in, and  
11 then it says "C/W tight mesh arm, tender to  
12 palpation, vagina is six centimeters depth."

13 Do you see that?

14 A Yes.

15 Q Do you, do you have an understanding of  
16 what he means when he writes "C/W" before "the  
17 tight mesh arm"?

18 A "Consistent with" is usually what we use  
19 that to mean.

20 Q Okay, and then just below that he  
21 writes, "Dyspareunia due to tight band of mesh  
22 arm," and then he points out "revision of mesh  
23 arm/release band" is his plan.

24 Do you see that?

25 A Yes.

1           Q     At this point Dr. Bercik had found that  
2     there was a band which would signify contracted  
3     scar-plated mesh within her pelvis where the mesh  
4     arm is; correct?

5                     MR. COMBS: Object to form.

6                     THE WITNESS: Certainly that  
7     finding could be consistent with that.

8     BY MR. SLATER:

9           Q     And he confirmed, based on his exam,  
10    that that was the location where she was feeling  
11    pain, because he palpated on the hardened mesh;  
12    correct?

13          A     He palpated that that area was tender.  
14    It didn't -- he doesn't indicate whether or not  
15    that also reproduced the patient's complaints of  
16    dyspareunia.

17          Q     Now let's turn to the next two pages  
18    later, which is the next surgery. I'm now going  
19    to ask you about the February 20, 2009 operative  
20    report for a couple minutes.

21                     Dr. Bercik in that report indicates a  
22    preoperative diagnosis of dyspareunia and vaginal  
23    stricture; correct?

24          A     Yes.

25          Q     And the dyspareunia and vaginal

1 stricture was due to the Prolift; correct?

2 MR. COMBS: Object to form.

3 THE WITNESS: Was due to the  
4 surgery for the Prolift.

5 BY MR. SLATER:

6 Q Well, Dr. Bercik found on his exam a  
7 mesh band, he found a tight mesh arm, tenderness,  
8 and determined to operate to release and remove  
9 that mesh; correct?

10 A He found, he found a tight band, yeah,  
11 and that's what he was -- that was tender. That's  
12 what he was operating on, yes.

13 Q The procedure that was performed on Pam  
14 Wicker was the Prolift procedure. That's the  
15 procedure she had performed; right?

16 A Yes.

17 Q And as a result of that procedure, the  
18 Prolift procedure, she was now suffering from  
19 dyspareunia and a vaginal stricture, according to  
20 Dr. Bercik's operative report; correct?

21 A I can't say that the vaginal stricture  
22 was due to the Prolift itself. She's had surgery,  
23 including with a Prolift, so the mesh portion  
24 clearly is going to be related to the Prolift. If  
25 there is scarring or stricturing or scar bands

1 without the mesh portion there that's causing any  
2 type of constriction or whatever he calls it, I  
3 can't say whether that's specifically from Prolift  
4 versus just surgery itself.

5 Q If you -- you've read through his  
6 operative report before; right?

7 A Yes.

8 Q Dr. Bercik actually found that the areas  
9 of stricture corresponded to areas of tight,  
10 tensioned mesh that was contracted that he  
11 released and removed; correct?

12 A Certainly the -- he talks about that the  
13 11:00 was related to a band of mesh. The 2:00, he  
14 says there was a stricture that he ended up  
15 opening to excise the strictured area. He talks  
16 about an erosion was identified, but it's unclear.  
17 I mean he talks about the erosion being from the  
18 mesh. He doesn't talk about the stricture being  
19 from the mesh.

20 Q Did you read his deposition?

21 A Yes, I did.

22 Q And you read where he said that on both  
23 sides he cut tension bands of mesh?

24 MR. COMBS: Object to form.

25 THE WITNESS: I think I recall



1 reading that, yes. I'm just -- I'm doing it  
2 based on his operative note that you asked  
3 me.

4 BY MR. SLATER:

5 Q Well, if you take together the operative  
6 note and Dr. Bercik's testimony explaining what he  
7 documented, he found that both of the strictures  
8 were due to tensioned, contracted, scarred mesh;  
9 correct?

10 MR. COMBS: Object to form.

11 THE WITNESS: With both of those  
12 included, that was his conclusion, or that  
13 was his findings.

14 BY MR. SLATER:

15 Q And both of those were due to the  
16 Prolift being in Pam's body; correct?

17 A Yes.

18 Q He also -- rephrase.

19 Dr. Bercik also found on February 20  
20 eroded mesh, and he removed that as well; correct?

21 A A 2-millimeter area of erosion he  
22 removed, yes.

23 Q And erosion was due to the Prolift;  
24 correct?

25 A I guess so. The mesh that was there was

1 the Prolift mesh, yes.

2 Q Let's flip forward to the next office  
3 visit, April 2, 2009. Dr. Bercik documented on  
4 April 2, 2009, that if --

5 A Excuse me. Just a second. I'm just  
6 making sure I'm on the right page.

7 Okay. Thank you.

8 Q It's got a 71 at the bottom.

9 A That's fine.

10 Q Okay.

11 The first visit documented after  
12 February 20 is April 2.

13 Do you have that in front of you?

14 A Yes.

15 Q And at that point, following the release  
16 and removal of contracted mesh and eroded mesh,  
17 Mrs. Wicker indicated she was feeling well and  
18 that she didn't have pain at that point; correct?

19 A Correct.

20 Q That would confirm that it was the mesh  
21 that was causing her pain, since by removing the  
22 mesh, the pain went away.

23 That makes sense; right?

24 MR. COMBS: Object to form.

25 THE WITNESS: It certainly is one

1           cause that she could be having for pain.

2       BY MR. SLATER:

3           Q     Dr. Bercik documents that she has a  
4       shortened posterior wall at 6 to 7 centimeters.

5                     Do you see that?

6           A     Yes.

7           Q     You would agree a vagina that has a  
8       length of 6 to 7 centimeters is a shortened  
9       vagina?

10          A     It is on the -- it is in the -- it's the  
11       lower limits or lower areas of what we would  
12       typically think of as vaginal length. I think to  
13       some extent it would depend on the partner.

14          Q     Let's turn forward now to the next  
15       visit. Turn to April 28, 2009.

16                     On April 28, 2009, Pam returned to  
17       Dr. Bercik; correct?

18          A     Yes.

19          Q     She now reports that she "has  
20       dyspareunia and bladder pain after exercise,  
21       pressure-like pain, discomfort, symptoms of a  
22       possible yeast infection. Now on Cipro."

23                     Do you see that under the comments  
24       section?

25          A     Yes, yes.

1           Q     An exam was performed, and Dr. Bercik  
2     confirmed that the vagina was estrogenized, so she  
3     was using the estrogen; correct?

4           A     Yes.

5           Q     Dr. Bercik also confirmed that the  
6     incision for the surgery was intact; right?

7           A     Yes.

8           Q     Dr. Bercik documents that he felt --  
9     well, rephrase.

10                     Dr. Bercik says under the physical exam,  
11     "Mesh felt 2/3 along vaginal wall anterior, apical  
12     part of vagina with prolapse to minus 3 with  
13     standing, mesh [is] not tender to palpation."

14                     Do you see that?

15           A     Yes.

16           Q     So he's confirming that he felt mesh  
17     along the anterior vaginal wall by palpation;  
18     correct? That's what that means?

19           A     Again, one would assume that he's  
20     meaning he feels that under the vaginal wall  
21     rather than through the vaginal wall, since he  
22     doesn't say "erosion," but yes, I would assume  
23     that it's -- he's feeling that there's mesh under  
24     the vaginal wall.

25           Q     Where he writes "apical part of vagina

1 with prolapse to minus 3," what does that  
2 correlate to in terms of stage 1, stage 2, stage  
3 3?

4 A For the apex? I think she would be in  
5 this case probably a stage 2.

6 Q So at this point following the Prolift  
7 surgery, she's now beginning to re prolapse;  
8 correct?

9 A Yes.

10 Q The arms of the Prolift have a  
11 particular purpose in that procedure; correct?

12 A Yes.

13 Q One of the purposes of the arms is to  
14 provide support to prevent a re prolapse of an  
15 organ; correct?

16 A Yes.

17 Q By cutting the arms to treat the  
18 contraction and the tension bands, that is  
19 weakening the intended support from the Prolift  
20 and making it more likely to end up with a  
21 re prolapse; correct?

22 A I think there is certainly a possibility  
23 that the patient could have a re prolapse of the  
24 apex if you cut the armbands.

25 Q In Pam Wicker's case, you would agree

1 with me that certainly the fact that the arms were  
2 cut and some of the arms were removed was at least  
3 a contributing factor to her ending up with a  
4 re prolapse of her bladder; correct?

5 MR. COMBS: Object to form.

6 THE WITNESS: I think that that's a  
7 reasonable statement.

8 BY MR. SLATER:

9 Q Okay.

10 That was the last time that Dr. Bercik  
11 saw Pam Wicker; correct?

12 A That's correct.

13 MR. SLATER: Okay.

14 Let's go to number 10, folder 10,  
15 and mark it as the next exhibit, which I  
16 guess puts us at 15.

17 (Exhibit 15 was marked for  
18 identification.)

19 BY MR. SLATER:

20 Q Exhibit 15 is the operative report from  
21 Dr. Raz for his first surgery on Pam, July 9,  
22 2009.

23 Do you see that?

24 A It's just in a little different format  
25 than what I've seen, so give me a second.

1 Okay.

2 Q The first thing Dr. Raz does in this  
3 operative report is he describes a preoperative  
4 diagnosis.

5 Do you see that at the top?

6 A Yes.

7 Q He indicates at that point that Pam had  
8 "vaginal shortening post-hysterectomy, severe  
9 vaginal pain and dyspareunia, and complications of  
10 anterior mesh surgery for cystocele with prior  
11 vaginal erosion."

12 Do you see that?

13 A Yes.

14 Q And that's a reasonable preoperative  
15 diagnosis based on Pam's clinical course at that  
16 point; correct?

17 MR. COMBS: Object to form.

18 THE WITNESS: It is a diagnosis  
19 based on what he's saying he saw on exam and  
20 based on what she's telling him symptom-wise,  
21 so I think it would be consistent.

22 BY MR. SLATER:

23 Q Let's go now to the indications for the  
24 surgery.

25 Dr. Raz first indicates "Mrs. Wicker

1 suffers from significant complications after a  
2 prior Prolift surgery for cystocele."

3 That's a statement you would agree with;  
4 right? At that point that was accurate?

5 A Again, significant? Yeah, I would  
6 probably say that she's certainly suffering from  
7 complications from it.

8 Q Would you agree that the complications  
9 at this point are significant where she's now  
10 facing her second operation, post Prolift?

11 A I think from her perspective, they  
12 probably were significant, yes.

13 Q From your perspective as a physician  
14 familiar with the Prolift procedure, do you look  
15 at her course, she's now facing her second  
16 post-Prolift operation, would you agree these are  
17 significant complications at this point?

18 A Again, I mean it, it's certainly -- I  
19 guess I would say significant. I mean it's, it's  
20 not the level of significance of other  
21 complications that we see, but, you know, again,  
22 "significant" is going to be a relatively  
23 subjective term.

24 Q Dr. Raz points out that "on physical  
25 examination, the vagina was extremely short, half



1 of the normal size."

2 So there he's talking about the vaginal  
3 shortening; correct?

4 A Correct.

5 Q Dr. Raz points out, "We can see white  
6 spots of irregular intraepithelial elevations that  
7 are mesh induration in the anterior vaginal wall."

8 So he saw that on his actual physical  
9 exam of her vagina; correct?

10 A Yes.

11 Q Dr. Raz says, "We found also mesh in the  
12 periurethral area, with significant scarring of  
13 the vagina."

14 That is something he found on his exam;  
15 correct?

16 A That's what he's reporting.

17 Q He then points out that, "Prior MRI  
18 shows a cystocele grade 3 to 4, minimal urethral  
19 hypermobility, and the ultrasound of the vagina  
20 shows folded irregular mesh in the anterior  
21 vaginal wall."

22 Do you see where I'm reading from?

23 A Yes, I see that.

24 Q Did you look at the MRI?

25 A Yes.

1 Q Did you agree it showed a cystocele  
2 grade 3 to 4 at that point?

3 A I, I think that there is anterior wall  
4 relaxation and a cystocele. I'm not sure that I  
5 would call it grade 3 to 4. It depends on the  
6 grading system you use, and he doesn't specify  
7 that.

8 Q Did you view the actual ultrasound of  
9 the vagina he's pointing to?

10 A With the folded arm or whatever he's  
11 talking about, yes, I saw the photos.

12 Q Was the irregular mesh in the anterior  
13 vaginal wall part of the ultrasound?

14 A I saw the, the picture of the folded  
15 mesh. It wasn't clear to me that it was  
16 specifically in the anterior wall versus in the  
17 tunnels from where the arms were placed.

18 Q But it was one or the other location?

19 A I'm sorry?

20 Q You felt it was either the anterior wall  
21 or in the tunnels where the arms had been placed,  
22 one or the other?

23 A Yeah, that's -- it would have to be one  
24 or the other.

25 Q We could certainly agree that folded

1 Prolift mesh is not something that you want within  
2 a woman's body under these types of circumstances  
3 or any circumstances; right? You want the mesh to  
4 lay flat?

5 A Yeah, ideally you want the mesh to lay  
6 flat. It doesn't always, but you want it to.

7 Q -- "risk of contraction and formation of  
8 scar plating and bridging"; correct?

9 MR. COMBS: You cut out.

10 THE WITNESS: You cut out in the  
11 beginning.

12 BY MR. SLATER:

13 Q No problem.

14 When the mesh is folded, as described  
15 here and as shown on the ultrasound, that creates  
16 an increased risk to end up with scar plating and  
17 bridging fibrosis, because you have the mesh  
18 folded and bunched together; correct?

19 MR. COMBS: Object to form.

20 THE WITNESS: I'm not sure that you  
21 can make that causative statement.

22 BY MR. SLATER:

23 Q Well as a general proposition you would  
24 agree with that statement; right?

25 A I, I mean I'm not going to say that I

1 agree with the fact that there's more scar plating  
2 and all that kind of stuff. I said with the mesh  
3 folded -- let's go back. Why don't you ask the  
4 question again so I make sure I answer it  
5 correctly, or if you want to read back --

6 Q When there's folding -- yeah, I'll ask  
7 it again. When the, when the Prolift mesh is  
8 folded like this, it increases the risk to end up  
9 with plates of scar tissue or bridging fibrosis,  
10 because the mesh is bunched together and folded  
11 together; correct?

12 MR. COMBS: Object to form.

13 THE WITNESS: Again, I don't think  
14 that you can say that statement, that it  
15 increases the risk of that and/or that it is  
16 because of that.

17 BY MR. SLATER:

18 Q Do you know the viewpoint of Ethicon  
19 Medical Affairs on that --

20 A No.

21 Q -- subject of that question?

22 A No, I do not.

23 Q You know who -- I'm sorry. You know who  
24 Dr. Raz is; am I correct?

25 A Yes.

1 Q Have you ever met him?

2 A I've worked with him, yes. He was a  
3 member of the committee I chaired.

4 Q Which committee was that?

5 A For the American Board of Obstetrics and  
6 Gynecology, the committee that was the fellowship  
7 accreditation program for female pelvic medicine  
8 and reconstructive surgery. I was the chair and  
9 he was a member.

10 Q Would you agree with me that, to the  
11 best of your knowledge, Shlomo Raz has probably  
12 treated more mesh complications in more patients  
13 than any doctor in the United States?

14 A I can't make that statement.

15 Q Is there any other doctor you can  
16 suggest has treated anywhere close to the number  
17 of patients he has with mesh complications?

18 A There are -- there's one other physician  
19 group that's in Atlanta that puts itself forward  
20 as being the premier or prime group for mesh  
21 complications. I don't know what their numbers  
22 are compared to Dr. Raz.

23 Q Dr. Miklos and Moore; correct?

24 A Correct.

25 Q You read Dr. Raz's testimony that he's

1 removed mesh from -- I believe the number was over  
2 400 women. Correct?

3 A I think that's what he stated, yes.

4 Q Would you -- rephrase.

5 Would you agree with me that Dr. Raz is  
6 considered within the medical community to be the  
7 foremost expert in the United States with regard  
8 to the treatment of mesh complications?

9 MR. COMBS: Object to form.

10 THE WITNESS: I would not agree to  
11 that statement at all.

12 BY MR. SLATER:

13 Q Do you have respect for Dr. Raz's  
14 knowledge and understanding in the area of  
15 treating mesh complications?

16 A That's -- I would really prefer not to  
17 answer that question if at all possible on the  
18 record.

19 Q You need to answer.

20 A Do I have respect for his ability to do  
21 that? No.

22 Q I think you told me you've treated  
23 between 10 and 20 patients maybe total in your  
24 career with mesh complications at the prior  
25 deposition?

1           A     It's possible. If I said that at the  
2     prior deposition, that's certainly possible.

3           Q     As you sit here now, if I ask you how  
4     many patients with mesh complications you've  
5     treated for those complications, would you tell me  
6     a different number than ten to 20?

7           A     I think it's probably going to be on the  
8     higher side of ten to 20, but it may be up even to  
9     30, but it's not going to be, you know, 400, no.

10          Q     What's your issue with Dr. Raz? You  
11     said you don't respect him or words to that effect  
12     with regard to mesh removal. What is the issue  
13     you have?

14          A     Your, your question was slightly  
15     different phrased -- differently phrased than  
16     saying I just don't respect him for mesh removal.

17                 I think that there are a number of  
18     different issues that I have with Dr. Raz. I  
19     think that, first of all, when you approach a  
20     problem, and your main approach is to be a surgeon  
21     and cut something out, you have this tendency to  
22     then repetitively go back and cut something out,  
23     even when there might be other alternatives that  
24     the patient could be treated with, and so that  
25     sometimes as surgeons we are a little overly

1     zealous about when we decide to operate rather  
2     than deciding to not operate.

3             I think that there are other ways to  
4     approach some of the mesh complications that would  
5     potentially be less invasive for a patient, that  
6     he doesn't really bring into play. If the mesh is  
7     there, he cuts it out. I think that that can  
8     sometimes create problems that -- additional  
9     problems, shall we say, that may have been avoided  
10    had they not done that.

11            In addition, you know, Dr. Raz on one  
12    side of the equation is talking about the  
13    horrendous aspects of mesh and the problems and  
14    it's the worst thing in the world to put in the  
15    vagina, despite the fact that he has put that in  
16    the vagina in a fair number of women over the  
17    years of his career, even within, you know, a  
18    couple of years prior to the time that Pam Wicker  
19    had her procedure.

20            He typically doesn't report his  
21    complications or problems with it, so it becomes  
22    very difficult to then know whether the  
23    complications are mesh-dependent, the  
24    complications that are surgeon-dependent, et  
25    cetera. I think that -- well, I think I'll stop



1 at that point.

2 I just think that, you know, sometimes,  
3 similar to Miklos' group, I've seen patients where  
4 it would have been much better had the aggressive  
5 surgeon not chosen to operate on the patient, and  
6 they left the patient in worse shape than if they  
7 had not operated at all.

8 Q There's a difference of opinion among  
9 certain surgeons out there about whether or not  
10 it's -- one should remove mesh when a woman is  
11 suffering from complications that are mesh-related  
12 as opposed to trying conservative therapy?  
13 There's a difference of opinion; correct?

14 A Yes.

15 Q And ultimately it comes down to the  
16 judgment of the surgeon who is treating the  
17 patient to determine what's the best course to  
18 recommend; right?

19 A With their own particular bias that they  
20 have, yes.

21 Q Well, every doctor has their own biases  
22 and experience that enters into their judgment?  
23 Everybody has that; right?

24 A Correct, but again, if you are only  
25 focused on offering one form of therapy for a

1 patient, you're going to offer that form of  
2 therapy.

3 Q Are you under the impression that  
4 Dr. Raz recommends surgery to every woman that  
5 goes to him to consult with mesh complications?

6 A No.

7 Q So, and in fact, you know Dr. Raz  
8 doesn't offer surgery to every woman who comes to  
9 him with complications. Some of them he  
10 recommends conservative treatment; right?

11 MR. COMBS: Object to form.

12 THE WITNESS: I understand that  
13 that is the case, yes.

14 BY MR. SLATER:

15 Q In this case --

16 THE VIDEOGRAPHER: Two minutes left  
17 on this tape, counsel.

18 MR. SLATER: Why don't you change  
19 it then.

20 THE VIDEOGRAPHER: Thank you very  
21 much. At 2:43 off record, ending disc number  
22 2 in our continuing deposition of  
23 Dr. Horbach.

24 (Whereupon, a short recess was  
25 taken.)

1 THE VIDEOGRAPHER: At 2:52 on  
2 record, now 2:53, beginning disc 3 in our  
3 continuing deposition of Dr. Horbach.

4 BY MR. SLATER:

5 Q Dr. Horbach, looking again at the  
6 July 9, 2009 operative report, Dr. Raz talks about  
7 the procedure, and about four lines down in that  
8 section he starts by saying, "We felt immediately  
9 the induration and the infiltration of the mesh in  
10 the superficial epithelial layer of the vagina.  
11 All the spotty white areas are actually  
12 intraepithelial infiltration of mesh."

13 Do you see that?

14 A Yes.

15 Q So he's describing that he clinically  
16 found during the operation that the mesh was  
17 eroding through the vaginal wall?

18 A I assume that that's what he's stating.  
19 I mean he took pictures showing these little white  
20 spots, and I assume that that's what he's  
21 referring to were these white spots with  
22 infiltration of mesh.

23 Q You're not denying that that's what that  
24 is, are you?

25 A No.

1           Q     He points out in his operative report,  
2     "The mesh was dissected sharply from the vaginal  
3     wall, extended laterally toward the obturator  
4     fascia."

5                     Do you see that?

6           A     Yes.

7           Q     So when he was operating, he's actually  
8     dissecting into the obturator area on both sides  
9     ultimately; correct?

10          A     Not necessarily into. He's dissecting  
11     towards it.

12          Q     Okay.

13                     Dr. Raz dissected towards the obturator  
14     area on both sides; correct?

15          A     I don't know that he did both sides,  
16     because he doesn't necessarily say bilaterally,  
17     but it says that at least one side he did.

18          Q     Let me also ask you one question, just  
19     going back.

20                     The arms of the anterior Prolift, would  
21     they have extended into the vicinity of the  
22     levator ani?

23          A     It depends on how they were placed.  
24     Theoretically, if you're talking about the  
25     pubococcygeus muscle, the posterior -- I mean the

1 superior arms of the anterior Prolift should more  
2 be a little more laterally to the pubococcygeus.  
3 In the distal arms of the anterior Prolift, those  
4 may come through part of the insertion of the  
5 pubococcygeus on pubic symphysis.

6 Q So in the operations now performed by  
7 Dr. Bercik and Dr. Raz, they're operating at least  
8 in the area of the obturator and the levator ani;  
9 correct?

10 MR. COMBS: Object to form.

11 THE WITNESS: Well, actually, if  
12 he's, if he's dissecting primarily in the  
13 anterior wall, he's not going to be out to  
14 the levators. If he's dissecting the distal  
15 meshes towards the obturator fascia, he may  
16 or may not gone -- may or may not have gone  
17 actually to the insertion of the levators  
18 there.

19 So I mean he's going towards that  
20 area, yes.

21 BY MR. SLATER:

22 Q -- talking about distal, you're talking  
23 about the arms; correct?

24 A Yes, distal arms.

25 Q So Dr. Bercik we know is operating out

1 into the distal region when he was operating to  
2 treat the contractures of the arms in February?

3 A I'm -- I think for some reason I, my --  
4 the question is whether he was doing the distal or  
5 he was doing -- one would assume if it's  
6 3 centimeters above the hymen, he would be doing  
7 primarily the distal. So that means he would have  
8 cut those, and Raz is talking about dissecting out  
9 laterally toward the obturator fascia, but it's  
10 not really clear if he's talking about arms, if  
11 he's talking about the proximal distal ones or  
12 just the edge of the mesh itself.

13 Q Would you agree with me that the  
14 surgeries performed by Dr. Bercik in February '09,  
15 Dr. Raz in July of 2009, could contribute to  
16 causing pelvic floor myalgia in the obturator and  
17 levator ani regions?

18 MR. COMBS: Object to form.

19 THE WITNESS: Dissection in those  
20 regions can contribute to levator myalgia,  
21 obturator internus myalgia, yes.

22 BY MR. SLATER:

23 Q To the extent that you found or opined  
24 that Pam Wicker has or has had pelvic floor  
25 myalgia, would you agree with me that these

1 dissections that Dr. Bercik and Dr. Raz did over  
2 the course of time are likely contributing factors  
3 to that?

4 A They are a contributing. I don't think  
5 they're the most contributing.

6 Q Let's go back to Dr. Raz's operative  
7 report of July 9. He points out that "the mesh we  
8 found covered only the distal half of the  
9 bladder."

10 What is he describing there? What does  
11 that mean?

12 A That's a good question, other than I  
13 would assume what he's meaning is that the portion  
14 of the anterior wall just above the ureterovesical  
15 junction, usually that would probably be the  
16 distal portion of the area for the bladder, was  
17 where there was mesh, and that the proximal  
18 portion, sort of the upper part of the anterior  
19 vaginal wall, he did not identify any mesh there.

20 Q -- that is a consequence of the release  
21 of the arms by Dr. Bercik?

22 A I can't necessarily say that, because  
23 theoretically, if Bercik released the distal arms,  
24 that doesn't explain why it's not found in the  
25 proximal portion of the bladder.

1           Q     Let me ask you this. The Prolift, when  
2     it's -- well, rephrase.

3                     The intent is for the Prolift to be  
4     covering both the distal and proximal part of the  
5     bladder; correct?

6           A     Correct.

7           Q     And for whatever reason, by July of 2009  
8     Dr. Raz found it was not covering the proximal  
9     half of the bladder and that this is where she had  
10    bladder prolapse; correct?

11          A     Correct. That's what he states in this.

12          Q     -- reasonable degree of medical  
13    probability --

14          A     I'm sorry.

15          Q     -- as to --

16          A     You cut out.

17          Q     That's fine.

18                     Do you have an opinion to a reasonable  
19    degree of medical probability as to why the mesh  
20    was no longer covering the proximal half of the  
21    bladder at this point?

22          A     I can give you several reasons about  
23    why. I don't know that I can give you which of  
24    those is the most likely cause.

25          Q     What would you say are the likely



1 causes?

2           A     The -- it is possible that the proximal  
3 edge of the anterior mesh was not adequately fixed  
4 to the vaginal cuff. It is possible that it was  
5 fixed to the cuff but that you can get separation  
6 a part of the pubocervical fascia from the cuff,  
7 and it retracts down, and you don't have  
8 pubocervical fascia in the upper portion of the  
9 anterior wall, and the prolapse comes around that.  
10 It is possible that Bercik's surgery caused  
11 disruption of the position of the original  
12 prolapse, and as a result, it wasn't covering the  
13 upper portion of that area.

14                     I think those are probably the likely  
15 causes.

16           Q     Whichever one or a combination of those  
17 causes it would be, they would all be related in  
18 some way to the Prolift itself; correct?

19                     MR. COMBS: Object to form.

20                     THE WITNESS: The Prolift itself or  
21 the manner in which it was placed.

22 BY MR. SLATER:

23           Q     The re prolapse -- well, rephrase.

24                     The prolapse of Pam Wicker's bladder --  
25 you didn't hear me again?

1           A       No. I was going to actually stop.

2                   Going back to the last question you  
3       said, of the different theories that I have given  
4       for why that's the case, the not properly fixing  
5       the Prolift wouldn't be the Prolift's fault.  
6       Reoperating and distorting it -- I mean you're  
7       reoperating because of the Prolift, but the  
8       distortion isn't necessarily the Prolift's fault.  
9       The pulling down of the pubocervical fascia can  
10      happen with or without Prolift there.

11                  So I mean there can be an association of  
12      Prolift with those things, but there also can be  
13      those things happening without it being something  
14      wrong with the Prolift itself.

15                  Does that clarify things?

16           Q       Definitely, now that I understand.

17                  Whichever one of these causes it was,  
18      ultimately the prolapse of Pam Wicker's bladder  
19      after the Prolift had been put in was a  
20      complication related to, for whatever reason, the  
21      Prolift no longer covering the bladder as  
22      intended; correct?

23                  MR. COMBS: Object to form.

24                  THE WITNESS: That is correct.

25

1 BY MR. SLATER:

2 Q Dr. Raz in his July 9 operative report  
3 talks about "reapproximating" Pam's vagina, trying  
4 to treat the shortening and performing a vault  
5 suspension procedure; correct?

6 A Yes, I see that.

7 Q Dr. Raz determined that he would attempt  
8 to lengthen the vagina so that it would be  
9 possible for Pam Wicker to try to have sexual  
10 relations; correct?

11 A That's what he was attempting to do.

12 Q And that was a reasonable surgical  
13 judgment to attempt to do that; correct?

14 A It is an option. Another judgment would  
15 have been not necessarily to do it at the same  
16 time that you're dealing with a treatment of a  
17 mesh problem or mesh erosion because of the  
18 inflammatory component that may be there, and you  
19 may or may not get your optimal results.

20 Q When you're talking about the  
21 inflammatory component, you're talking about the  
22 inflammatory component of the Prolift mesh?

23 A Just the inflammatory component of the  
24 tissue you're dealing with that he's saying is  
25 indurated, et cetera, so it's a combination of

1     probably the tissue and the Prolift.

2                     Part of the difficulty -- part of the  
3     difficulty is that when you are trying to create a  
4     vaginal elongation after shortening, you have one  
5     of a couple options, and so if a vagina is  
6     contracted and scarred as he is suggesting is the  
7     case, then trying to lengthen that by stretching a  
8     somewhat noncompliant tissue is very often not  
9     going to be effective, because you're trying to  
10    pull and stretch something that he's saying really  
11    isn't stretchable, because it's restricted and  
12    constricted, et cetera.

13                    If you have a vagina that's nicely  
14    compliant and has a lot of give to it, then you  
15    may be able to lengthen the vagina by doing the  
16    types of suturing he's doing without adding a new  
17    lining for the vagina, but if you're trying to  
18    lengthen the vagina in a restricted vagina, you  
19    often have to place something over that new  
20    portion of the tunnel; otherwise, it just seals  
21    back up on its own. So you have to sometimes use  
22    a graft, whether it's an animal biologic type  
23    graft, like surgi-sist or like it's the patient's  
24    own tissues, like a skin graft.

25                    So he must have made the judgment that

1 her vagina had enough give and compliance and give  
2 and mobility and pliability to it that you could  
3 take something and stretch it to double its  
4 length, since he didn't add --

5 Q Dr. Raz -- I'm sorry. Dr. Raz describes  
6 the use of Vicryl sutures.

7 Those are absorbable; correct?

8 A They are absorbable, yes.

9 Q He indicates about halfway down on the  
10 second page of this operative report, "Interrupted  
11 sutures of 3-0 Vicryl were interlocked with  
12 lateral suspension sutures to provide a net of  
13 Prolene sutures to support the bladder, a total of  
14 four sutures are applied to the central defect."

15 Do you see that?

16 A Yes. Let me read back through that  
17 sentence again. I've read it before, but . . .

18 Okay. Yes, I see that.

19 Q -- defect, he's talking about the  
20 location where the bladder is actually prolapsing  
21 down and bulging into the vagina; correct?

22 A It's my -- yes. From what he's  
23 described, he's attempting to correct the area in  
24 the proximal portion of the anterior wall.

25 Q And he describes that he used a total of

1 four sutures, Vicryl and Prolene sutures that he  
2 used to create this net.

3 Is that your understanding?

4 A That is difficult to say that it was  
5 only -- that it was a combination of the, of four  
6 sutures between the two things or whether it was  
7 four only of one or the other, based on the way  
8 he's dictated.

9 The pictures from the operation seem to  
10 suggest that he's either very good about being  
11 able to conserve sutures or get, you know, a lot  
12 out with four sutures, or he put more than four  
13 in, because it looks like I could count more than  
14 that coming out of the defect.

15 Q So it could be that he used Vicryl and  
16 he used four Prolene sutures as well and didn't  
17 count the Vicryl? That's possible?

18 A It's possible. That I don't know, and  
19 the four sutures -- again, based on the pictures,  
20 you can use four sutures with needles, but you can  
21 cut it in half and you can use it more than just  
22 four times. That seemed to be the suggestion on  
23 the photograph when there was the spokes of the  
24 suture coming out.

25 Q With regard to Dr. Raz's surgical skill,

1 do you have a high level of respect for his skill  
2 as a surgeon performing this type of a procedure?

3 A I've never operated with him.

4 Q By reputation, is he considered to be  
5 highly skilled with this type of surgery?

6 A He presents or he publishes fairly high  
7 success rates with his surgeries.

8 Q This operation, the July 9, 2009  
9 operation, was performed to treat complications  
10 that resulted at the base level from the Prolift;  
11 correct?

12 MR. COMBS: Object to form.

13 THE WITNESS: I don't know that you  
14 can say it is from the Prolift. Again, it is  
15 a complication of a prolapse surgery. She  
16 had a recurrence in that area. Whether it  
17 was specifically Prolift-related or not, I  
18 can't say.

19 BY MR. SLATER:

20 Q Well, she didn't have another procedure,  
21 so you can't say that it was related to a  
22 different procedure, because she had the Prolift  
23 procedure; correct?

24 A Okay.

25 Your comment -- I'm referring to Prolift

1 as just a mesh. If you're referring to Prolift as  
2 the entire procedure, then we may be using  
3 different semantics.

4 Are you referring to it as the entire  
5 procedure?

6 Q In this question I am, yes.

7 A Then from the entire procedure, yes.  
8 From it being specifically the mesh-related,  
9 that's the one I can't say it's absolutely due to  
10 that.

11 Q And you understand, because you've  
12 performed the procedure and you've read the  
13 literature that was given to you when you were  
14 learning the Prolift, that there's a Prolift  
15 procedure, and the mesh and the instruments are  
16 provided by Ethicon to perform the Prolift  
17 procedure; correct?

18 A Correct.

19 Q So if you -- rephrase.

20 This surgery Dr. Raz performed in July  
21 of 2009 was to treat complications that resulted  
22 following from Prolift surgery that was done, and  
23 then I think you explained earlier some of this  
24 may have also been a result of the operation  
25 Dr. Bercik had performed earlier in 2009 to try to



1     treat Prolift complications earlier.

2                     Fair statement?

3             A     Yes, or it could have been from  
4     Dr. Bercik not performing the Prolift procedure in  
5     an optimal way originally, or it could have just  
6     been because it happens.

7             Q     Now, the surgical pathology report we  
8     have marked as -- it's folder 11. Let's mark it  
9     as the next exhibit.

10                     (Exhibit 16 was marked for  
11                     identification.)

12     BY MR. SLATER:

13             Q     Doctor, Exhibit 16 is the pathology  
14     report following the July 9, 2009 surgery by  
15     Dr. Raz.

16                     Do you have that in front of you?

17             A     Yes, I do. Can -- just for one second I  
18     want to check one thing relative to my record.

19                     Okay. Sorry. I just thought that this  
20     was slightly different than the report I had  
21     previously seen, but it's the same one.

22             Q     This pathology report from the July 9,  
23     2009 surgery describes "benign fibrovascular  
24     tissue with foreign body giant cell reaction."

25                     Do you see that?

1           A     Yes.

2           Q     And that just means that you have the  
3     mesh, there's fibrovascular tissue, which is scar  
4     tissue; correct?

5           A     Well, scar tissue can be fibrovascular,  
6     but fibrovascular tissue can also be not scar  
7     tissue, so . . .

8           Q     And there's a foreign body giant cell  
9     reaction that's part of the foreign body reaction  
10    to the mesh?

11          A     Yes.

12          Q     So at this point now in July of 2009,  
13    about nine months after the Prolift was originally  
14    put in, the pathology is showing that there is an  
15    ongoing chronic foreign body reaction; correct?

16          A     It is showing that there is a foreign  
17    body reaction. My -- the timing of when those  
18    giant cells showed up, whether they were early on  
19    and just persisted or, you know, a more recent  
20    event sort of implying a more chronic problem, I  
21    can't recall my pathology well enough to know how  
22    to separate that.

23          Q     You would agree with me that, based on  
24    the records you've seen, that there was a foreign  
25    body reaction to the mesh that was ongoing in July

1 of 2009 when the surgery was performed; correct?

2 MR. COMBS: Object to form.

3 THE WITNESS: I would agree that  
4 there was a foreign body reaction at the time  
5 of the surgery, yes.

6 MR. SLATER: Let's go to folder 13.

7 (Exhibit 17 was marked for  
8 identification.)

9 BY MR. SLATER:

10 Q Exhibit 17 is Dr. Raz's October 19, 2009  
11 operative report.

12 Do you see that?

13 A Yes. Let me just sort of go -- yes, I  
14 do see it.

15 Q And at this point Dr. Raz documents his  
16 preoperative diagnosis, "vaginal pain and vaginal  
17 erosion post prior mesh excision and vaginal  
18 reconstruction."

19 Do you see that?

20 A Yes.

21 Q And you would agree that's a reasonable  
22 preoperative diagnosis here at this point?

23 A I'm trying to recall the issue of her  
24 pain at that time. I mean he's saying that he has  
25 an erosion, so I would assume that that's the

1 case. Hang on.

2 In my notes from his office visit of  
3 September, just before this, she was reporting  
4 dyspareunia, not a consistent vaginal pain but a  
5 dyspareunia, and so the rest of it would be  
6 correct.

7 Q Dyspareunia would be pain in the vagina  
8 during sexual intercourse; correct?

9 A Correct.

10 Q Dr. Raz in his operative report -- I'm  
11 not going to go through it in detail, talks about  
12 removing granulating tissue and what he believed  
13 to be eroding mesh; correct?

14 MR. COMBS: Object to form.

15 THE WITNESS: That's what it says  
16 here.

17 BY MR. SLATER:

18 Q You would agree that this is treatment  
19 to treat a complication from a Prolift; correct?

20 A Based on his description, I can't say  
21 that that's indeed the case. He -- well, he  
22 describes dealing with an area where there is  
23 granulating tissue that's more in the proximal  
24 region where he was putting some of his sutures.  
25 He does describe seeing a small

1 ulceration of mesh, although it wasn't sent to  
2 pathology to be able to differentiate that that  
3 was indeed the case. So it's hard for me to know  
4 whether that granulating tissue is from the suture  
5 that he placed or from the previous placement of  
6 the Prolift.

7 Q Dr. Raz actually describes three  
8 different areas that he removed tissue and  
9 material from.

10 Do you see that?

11 A Let me go through it for three.

12 Q You'll see first he talks about the  
13 posterior --

14 A Correct.

15 Q -- vaginal wall, where he found  
16 granulating tissue leading to a small  
17 ulcerating -- ulceration of mesh.

18 Do you see that?

19 A Yes.

20 Q So that's, that's a mesh erosion;  
21 correct?

22 A Again, one would -- the location isn't  
23 where mesh would be at this point, so it's where a  
24 suture would be, so it's a little conflicting, and  
25 we don't have a pathology report to know if that

1 area that was removed was a reaction to mesh or a  
2 reaction to suture.

3 Q Dr. Raz calls it a "small ulceration of  
4 mesh." That's what he described it as; right?

5 A That's what he calls it as, yes.

6 Q Then just below that a few lines, it  
7 says, "In the right cuff of the vagina there is a  
8 one-millimeter area of minimal granulation  
9 suspicious of the beginning of a vaginal erosion,"  
10 and he excised that area?

11 A Correct.

12 Q Correct?

13 A Mm-hmm.

14 Q And then below he removed what he  
15 described as "an area of mesh that appeared a  
16 combination of mesh and sutures in the anterior  
17 vaginal wall"; correct?

18 A Correct.

19 Q At least in part this operation was to  
20 treat complications related to the Prolift being  
21 in Mrs. Wicker's body; correct?

22 A It was to treat -- it's difficult for me  
23 to say specifically. In the last area that he  
24 removed, it doesn't say that they were  
25 specifically erosions or whether he chose to

1     remove it. In the, in the second area that he  
2     removed, he removed it because there was  
3     granulation tissue and suspicion, although he  
4     doesn't say what material.

5                 In the first case, he says that he has  
6     granulation tissue with this small ulceration of  
7     mesh but in a place where mesh isn't supposed to  
8     be, based on what he's done in the previous  
9     surgery. So it's hard for me to say it's  
10    specifically that mesh was causing this at this  
11    particular time.

12                Q     Two questions about that.

13                   First of all, even if the doctor tries  
14    to remove the mesh in a certain area, there's no  
15    way for the doctor to be sure that they've gotten  
16    all the mesh out of that particular area; right?

17                A     It depends on where the area is.

18                Q     Let's talk about --

19                A     Sorry.

20                   In the arms I would agree that it is  
21    difficult, because it's down a tunnel, and you may  
22    have more difficulty being able to know that  
23    you've removed it.

24                   In the anterior/posterior vaginal wall,  
25    usually, most commonly, you're pretty sure whether

1 or not you've gotten the fibers and the mesh  
2 removed. I mean you can see that from his  
3 photographs that he took during surgery.

4 Q You can think that -- well, rephrase.

5 You can do your best to remove the mesh,  
6 you can visualize an area and think you've gotten  
7 the mesh, and it's common for more mesh to appear  
8 in an area. That happens all the time, doesn't  
9 it?

10 MR. COMBS: Object to form.

11 THE WITNESS: Not typically in an  
12 area of the anterior wall. Yes, in the more,  
13 you know, tunnel areas, possible, but usually  
14 if you've removed what you perceive as all  
15 the mesh material in that area, and you are  
16 as competent of a surgeon as Dr. Raz is put  
17 forward as, one would expect that you know  
18 whether you've excised all the mesh or not in  
19 that area.

20 And to get a --

21 BY MR. SLATER:

22 Q Are you familiar with --

23 A I mean to get granulation tissue of a  
24 centimeter and a half by, by half a centimeter, I  
25 mean that's not a small area of granulation



1 tissue. You're not going to have that kind of  
2 granulation tissue caused by a couple mesh fibers.

3 Q According to Dr. Raz, he visualized a  
4 small ulceration of mesh in the posterior -- what  
5 he described actually as the posterior part of the  
6 anterior part of the vaginal wall; correct?  
7 That's what he described in his deposition; right?

8 A That's what he's describing, yes.

9 Q The sutures that are now in Pam Wicker's  
10 vagina as of this time are sutures that were put  
11 in following surgeries -- were as part of  
12 surgeries that were performed to treat  
13 complications that followed from the Prolift  
14 surgery; correct?

15 MR. COMBS: Object to form.

16 THE WITNESS: I'm just trying to  
17 follow your sequence. The sutures, the  
18 permanent sutures he placed were an attempt  
19 to treat a complication/recurrence from the  
20 Prolift surgery, yes.

21 MR. SLATER: Let's go the folder  
22 15.

23 (Exhibit 18 was marked for  
24 identification.)

25 THE WITNESS: Can you give me just

1 a second so I can catch up with my notes?

2 BY MR. SLATER:

3 Q No problem. We're making good time now.

4 A Okay.

5 Q Exhibit 18 is the May 10, 2010 operative  
6 report.

7 You have that in front of you; right?

8 A Yes, I do.

9 Q At this point the preoperative diagnosis  
10 is "vaginal mesh erosion, post complications of  
11 mesh reconstruction of the vaginal wall." That's  
12 number one, and number two is "cystocele."

13 Do you see that?

14 A Yes.

15 Q That's a reasonable preoperative  
16 diagnosis for Pam Wicker at that point; correct?

17 A The first part is. I'm trying to look  
18 for my notes about whether he had evidence of a  
19 recurrent cystocele after his attempts at placing  
20 the Prolene netting. I'd have to look back at his  
21 office notes, which I don't have right this  
22 minute, to know whether the cystocele comment is a  
23 correct one as well, but the first one is correct.

24 Q Let's look at the Indications section.  
25 Bear with me for one second.

1 Rephrase.

2 In the Indications section, it appears  
3 that Dr. Raz actually combines the indication and  
4 the procedure note.

5 Do you see that?

6 A Yes.

7 Q He starts off and says that "Mrs. Wicker  
8 is a patient suffering from complications of prior  
9 mesh surgery."

10 You would agree with that statement;  
11 correct?

12 MR. COMBS: Object to form.

13 THE WITNESS: Yes.

14 BY MR. SLATER:

15 Q Dr. Raz points out, "This time she  
16 presented with erosion of mesh that extends from  
17 the obturator area in the right, to the left, with  
18 two areas of erosion in the vaginal wall laterally  
19 of an extent of 1.5 centimeters in each side."

20 See where I'm reading from?

21 A Yes.

22 Q Would those erosions be erosions of mesh  
23 from the area where the arms would be?

24 A Most likely, yes.

25 Q And that's in the area of the obturator,

1 as he described?

2 A He doesn't really specify whether he's  
3 distal or proximal, but yes, he could be in -- in  
4 either place he could be near the obturator.

5 Q Dr. Raz described the removal of the  
6 eroded mesh. He describes the incisions he  
7 performed; correct?

8 A Yes.

9 Hang on two seconds here.

10 Based on where he's placed the  
11 incisions, it looks as if it's probably the distal  
12 arms.

13 Q Okay.

14 A Okay.

15 Q You would agree with me that the surgery  
16 to treat the -- well, rephrase.

17 You would agree that the eroding mesh  
18 described here in this operative report is a  
19 complication from the Prolift; correct?

20 A It is the Prolift mesh, yes.

21 Q And the surgery to remove the eroding  
22 mesh is a reasonable surgical judgment to remove  
23 eroding mesh; correct?

24 A Yes.

25 Q After Dr. Raz removes the eroding mesh,

1 he then talked about reconstructing the vaginal  
2 wall and urethra with Vicryl sutures.

3 Do you see that?

4 A Yes.

5 Q And again, that was a reasonable  
6 surgical step to take after dissecting the mesh  
7 out?

8 A Again, it would depend upon the anatomy.  
9 He doesn't describe an anatomic problem that he's  
10 plicating, but assuming there is an anatomic  
11 problem, you can certainly plicate it.

12 Q Do you have any reason to believe that  
13 the reconstruction vaginal wall and urethra was  
14 not necessary at this point, anything in the  
15 records or documents?

16 A Again, I'd have to pull his pre-, his  
17 exam previous to this to see what the anatomy  
18 shows per se to see if there was any potential  
19 relaxation in that area.

20 Do you have the -- do you have that?

21 MR. COMBS: No.

22 THE WITNESS: Hang on. Let me see  
23 if I have it in my notes. They're  
24 unfortunately not quite in order.

25 I'm just having a little bit of

1           difficulty locating the physical exam that  
2           was done prior to that. It's hard to tell,  
3           because this one that I have indicates it  
4           was -- the date stamp on the top is actually  
5           three days after the surgery, so it's hard to  
6           know if that was the pre-op one, just  
7           post-dated.

8                         But anyway, if he found an area of  
9           relaxation there, it would be appropriate to  
10          plicate it.

11         BY MR. SLATER:

12                 Q       According to the operative report,  
13       there's a post-operative diagnosis confirming  
14       there was a cystocele grade 2 to 3, so presumably  
15       Dr. Raz confirmed that during the surgery?

16                 A       Well, the hard part is during the  
17       surgery you really can't confirm that so much,  
18       because once the patient is under relaxation,  
19       everybody looks like they have a cystocele. So he  
20       would have hopefully confirmed that in a  
21       preoperative exam with the patient awake.

22                 Q       Okay.

23                         This surgery ultimately was performed to  
24       treat complications that resulted from the Prolift  
25       being in her body; correct?

1 MR. COMBS: Object to form.

2 THE WITNESS: Yes.

3 MR. SLATER: Let's go to folder 17.

4 (Exhibit 19 was marked for  
5 identification.)

6 MR. SLATER: We don't even have to  
7 use this. Let's skip to the next one, the  
8 one in folder 18.

9 (Exhibit 20 was marked for  
10 identification.)

11 BY MR. SLATER:

12 Q This is the next operative report.

13 A Wish they would keep their format the  
14 same so I wouldn't keep getting confused with  
15 finding where the dates are.

16 Q Now, looking at Exhibit 20, that's the  
17 August 16, 2012 operative report for Dr. Raz?

18 A Correct.

19 Q His preoperative diagnosis is "mesh  
20 exposure, status post multiple surgeries for  
21 complications of mesh."

22 That's a reasonable preoperative  
23 diagnosis at this point; correct?

24 A Given that he's saying he found a  
25 granulating area, yes.

1           Q     Dr. Raz actually in his indications  
2     confirms that he found an area of "granulating  
3     ulceration, maybe 2 or 3 millimeters in size, in  
4     the distal left vaginal wall," and then in the  
5     description of the operation, he confirmed that he  
6     found that and actually removes that mesh?

7           A     Let me just make sure.

8                     Yes.

9           Q     This surgery was done to treat a Prolift  
10    complication involving eroding mesh; correct?

11          A     Yes. I mean assuming that this is mesh  
12    that he was removing, then -- ulceration with  
13    mesh, then yes, it was from the mesh that was put  
14    in for the Prolift.

15          Q     I want to change gears a little bit and  
16    ask you a few questions about Mrs. Wicker's  
17    medical, overall medical conditions, general  
18    medical conditions.

19                     Mrs. Wicker had breast implants and then  
20    later had the silicone breast implants removed and  
21    had saline implants put in.

22                     You're aware of that from her history;  
23    right?

24          A     Yes.

25          Q     That is of no significance to the



1 injuries and damages claimed in this case;  
2 correct?

3 MR. COMBS: Object to form.

4 THE WITNESS: Her breast implant  
5 and removal didn't cause her to have a  
6 problem with the Prolift surgery, correct.

7 BY MR. SLATER:

8 Q In 1995, Pam Wicker had a Bartholin's --  
9 and for our court reporter, that's  
10 B-A-R-T-H-O-L-I-N, apostrophe, S -- cyst.

11 That's of no significance to you in  
12 forming your opinions; correct?

13 A Correct.

14 Q In 1999 Mrs. Wicker underwent shoulder  
15 surgery to remove a bone spur.

16 That's of no significance to you in  
17 forming your opinions; correct?

18 A Now we start getting into some of the,  
19 you know, orthopedic issues and body mechanic  
20 issues, per se. I'm not sure that I can say that  
21 specific procedure was involved in this situation,  
22 but it's an indication of some component of --  
23 bony abnormalities I guess is the best way I can  
24 say it.

25 Q -- the removal of a bone spur in 1999;

1 do you have an opinion to a reasonable degree of  
2 medical probability that the existence of the bone  
3 spur or the surgery to remove it is connected in  
4 some way to the injuries that we're claiming in  
5 this case?

6 MR. COMBS: Adam, you cut out at  
7 the beginning of the sentence.

8 MR. SLATER: I'll start again.

9 BY MR. SLATER:

10 Q Mrs. Wicker having a bone spur in her  
11 shoulder in 1999 and having that surgically  
12 removed, are you saying to a reasonable degree of  
13 medical probability, that had some connection to  
14 her pelvic and vaginal issues since the Prolift  
15 was put in her body?

16 A Not in the way that -- I would answer no  
17 to the question the way you phrased it.

18 Q In February 2008, Mrs. Wicker underwent  
19 a cervical discectomy with fusion.

20 Do you have an opinion to a reasonable  
21 degree of medical probability that that has some  
22 causative connection to the conditions in  
23 Mrs. Wicker's pelvis and vagina since the Prolift  
24 surgery?

25 A I think that that -- the hard part with

1     this particular surgery is it certainly could play  
2     a role in part of the complex. It really depends  
3     to some extent, going back to that, was there any  
4     pelvic floor problems in her muscles at the time  
5     of her original surgery or was there not, the  
6     timing of her surgery with the neck issues. She  
7     then went through a three-month period of time of  
8     postoperative recuperation. She had the ability  
9     to do some level of exercise during that issue but  
10    really wasn't doing her full level of exercise.

11                 She was released to do that full level  
12    of exercise about six, maybe eight weeks prior to  
13    her presenting with her initial prolapse symptoms.  
14    If you then say that the prolapse symptoms are in  
15    part, the pain issues, et cetera, may have some  
16    role with her pelvic muscles. It certainly is a  
17    transition that we see where a -- some type of  
18    intervention procedurally that affects the body  
19    mechanics.

20                 She's not working -- she's not really  
21    working out at the same level, and she then begins  
22    to -- again, it's sort of that last camel or straw  
23    that broke the camel's back, and it creates the  
24    problems or starts the process of problems in the  
25    pelvic floor.

1                   So that is a conceivable portion of what  
2   was going on. It really depends upon whether or  
3   not, you know, there was the muscular activity  
4   going on at the time of the original surgery or  
5   not. If there was not any muscular activity, then  
6   I would say that surgery isn't necessarily  
7   related. If there was some muscular activity,  
8   then certainly there could be a component that  
9   this starts the process.

10           Q     -- confirmed for me earlier in the  
11   deposition you're not drawing the opinion that  
12   there was any pelvic muscle issues before the  
13   first Prolift surgery; correct?

14           A     Again, we have limited information about  
15   that, but the assumption again is that there  
16   wasn't that there, but, you know, I don't -- we  
17   can't go back and check that, so . . .

18           Q     Based on what you know and what you have  
19   available to you now, you're not drawing an  
20   opinion to a reasonable degree of medical  
21   probability that Mrs. Wicker had any pelvic floor  
22   muscular issues before the Prolift was put in;  
23   correct?

24                   MR. COMBS: Object to form.

25                   THE WITNESS: Again, I suspect she

1           may have. I can't prove to within a  
2           reasonable degree of medical certainty.

3       BY MR. SLATER:

4           Q     And based on that, the neck surgery in  
5       February of 2008 would not be of any significance  
6       with regard to her pelvic and vaginal issues after  
7       the Prolift; correct?

8                       MR. COMBS: Object to form.

9                       THE WITNESS: I can't say that,  
10       because, you know, this lady has, is sort of  
11       like -- I hate to say it. She's an  
12       orthopedic nightmare in terms of multiple  
13       different aspects of her body mechanics and  
14       skeletal system that are affected, and if you  
15       have one area that's affected and you begin  
16       to change position, posture, walking, gait,  
17       then you're going to potentially have this  
18       domino effect.

19                      This particular one with the neck  
20       surgery, I can't say for a specific degree of  
21       medical certainty. I think that the other  
22       components of her orthopedic history  
23       subsequent to that certainly could play a  
24       role in her persistence of symptoms.

25

1 BY MR. SLATER:

2 Q Talking just about the neck, you're not  
3 drawing an opinion to a reasonable degree of  
4 medical probability that her neck surgery in  
5 February 2008 is a cause of her pelvic and vaginal  
6 condition after the Prolift; correct?

7 A Again, the way that's stated  
8 specifically, I would say no.

9 Q Now, let's talk -- and I think we'll  
10 probably talk for a few minutes about this.  
11 Mrs. Wicker -- new question. Mrs. Wicker had hip  
12 replacement surgery August 25, 2010; correct?

13 A Yes.

14 Q Mrs. Wicker had been complaining of hip  
15 issues and hip pain since about 2004; right?

16 A Off and on, and although it's a little  
17 more consistently stated, within the two years  
18 prior to the replacement.

19 Q In 2007 Pam Wicker stopped running  
20 because of the pain in her hip; correct?

21 A At some point she did -- she didn't stop  
22 running. She reduced her running, and I'm just  
23 trying to remember when it was.

24 I think she, she had told me that around  
25 the 2008 time period was she had cut back from her

1 12 to 15 miles per week, but she did not tell me  
2 that she wasn't running, because I have here that  
3 before the Prolift surgery she's talking about  
4 kick boxing, running, weights, spinning, Pilates,  
5 all of those things before the 2008 surgery.

6 Q On page 12 of your report you point out  
7 that in September 2007 she presented to one of her  
8 doctors with a six-month history of right hip  
9 achiness and stiffness and reduced range of motion  
10 in her cervical spine, and because of her hip  
11 pain, she had eliminated running from her exercise  
12 routine.

13 Does that refresh your memory that based  
14 on your review of the records, Pam stopped running  
15 in September of 2007?

16 A It tells me that she wasn't running at  
17 that point in 2007, but according to what she told  
18 me when we were talking, she said -- I asked her  
19 what work she was doing before the Prolift  
20 surgery, and that's what she had told me. She had  
21 reduced her running from the long-distance  
22 portion, but she stated she was still doing  
23 running.

24 So at this point in 2007, she may have  
25 not been running for that period of time. Whether

1 she began running again to a more limited  
2 standpoint, that seems to be what her comments to  
3 me would imply.

4 Q From 2004 forward, Pam Wicker reported  
5 painful osteoarthritis in her hip to the point  
6 that it altered her exercise regimen; correct?

7 A From two thousand -- you said what time  
8 period? 2004 on? Hang on.

9 Q You say it on page 11, "In 2004 she was  
10 noted to have complaints of right hip pain." So  
11 I'm using that as -- at least as of that time she  
12 had hip pain?

13 A Yes, but she also has had that hip pain  
14 come and go at different periods of time, whereas  
15 in the beginning, she then -- as she became closer  
16 to the two years prior to the replacement, the hip  
17 pain had become more of a problem to the point  
18 where it was altering her gait.

19 Q According to your report, by January of  
20 2008 a doctor had recommended a hip replacement  
21 for her. Her condition was that severe; correct?

22 A Yes. Yes, I believe so.

23 Q What I want to get at is this: From at  
24 least 2004, Pam was complaining of hip pain in the  
25 right hip. There were evaluations that showed her



1 right leg was longer than her left leg.

2 A Correct.

3 Q And this was for at least four years  
4 before her Prolift; correct?

5 A That evaluation of the leg discrepancy,  
6 yes.

7 Q And during that entire time, four years,  
8 right up until the Prolift, there's no  
9 indication -- except in the two weeks before she  
10 saw Dr. Bercik when he was operating on her for  
11 prolapse, there's no indication of any pelvic or  
12 vaginal pain at all; right?

13 A I think so. I'm just trying to recall  
14 whether in any of her gyn stuff -- no, I think her  
15 gyn history prior to that point was not -- did not  
16 include pelvic pain.

17 Q Okay.

18 After the Prolift, Pam Wicker has  
19 complained of pelvic pain. Whether we say it's  
20 all the time or whether there had been a few  
21 periods where she said that she didn't feel it as  
22 much, she's fairly consistently and for long  
23 stretches of time complained of pelvic and vaginal  
24 pain; correct?

25 A Correct. Sometimes -- again, there is

1 some conflict, because there's Raz notes that say  
2 she's feeling well, she feels -- you know, she's  
3 doing well, she doesn't have pain, and then there  
4 are other notes or her report that she is still  
5 having symptoms.

6 Q To the extent and during the periods --  
7 rephrase.

8 To the extent Pam Wicker has complained  
9 of pelvic and vaginal pain after the Prolift  
10 surgery, you would agree with me that the Prolift  
11 is one cause of that pain and to the extent that  
12 you believe her hip issue or her leg length issue  
13 is contributing, that would be a contributing  
14 factor, they would all be combining together to  
15 lead toward the pain.

16 Is that essentially your opinion?

17 MR. COMBS: Object to form.

18 THE WITNESS: I think that there,  
19 that it is a combination of factors that are  
20 leading to her pain. How much of her pain is  
21 or is not related to the specific Prolift  
22 and/or mesh is difficult for me to say, but I  
23 don't think that, certainly not at the  
24 present time or in the recent past, that  
25 that's the primary problem.

1 BY MR. SLATER:

2 Q You believe the Prolift and the Prolift  
3 mesh is a contributing factor. You also think her  
4 hip and her leg length issue is a contributing  
5 factor as well, and you're not going to tell me,  
6 you know, this is that percent or this is that  
7 percent. It's just they all contribute.

8 Is that fair?

9 A No, that's not what I said. I said all  
10 of that is correct except for this issue where you  
11 said my comment about the Prolift is, as an  
12 absolute, a contributing factor, and I think that  
13 it could be, but I'm not saying that it's an  
14 absolute. I'm not saying yes for sure.

15 Q More likely, more likely than not, to  
16 the extent that Pam Wicker has complained of  
17 vaginal and pelvic pain, the Prolift, the  
18 complications she has suffered related to the  
19 Prolift, and the surgeries to treat those  
20 complications are a substantial contributing  
21 factor; correct?

22 A I don't agree with all of that  
23 statement. I think that the original issues of  
24 the pain with the band that she originally had cut  
25 by Bercik in the beginning certainly was a

1 contributing issue for the pain, but it is  
2 difficult for me to say in the more subsequent  
3 episodes where she's having symptoms that it is --  
4 that the Prolift is involved in that.

5 Q Whatever hip issues and leg length  
6 issues Pam Wicker had before the Prolift, they  
7 caused her no pelvic pain and no vaginal pain,  
8 according to the records; correct?

9 A That's correct.

10 Q It was only after Pam Wicker had a  
11 Prolift put in her body, suffered complications  
12 connected to the Prolift, had one operation by  
13 Dr. Bercik to remove mesh, four operations in the  
14 operating room by Dr. Raz to remove mesh; it  
15 wasn't until all of the issues with the Prolift  
16 manifested that she began to complain of pelvic  
17 and vaginal pain; correct?

18 MR. COMBS: Object to form.

19 THE WITNESS: There is a temporal  
20 relationship, but you cannot say there's a  
21 causal relationship.

22 THE VIDEOGRAPHER: I'm sorry. I  
23 have to change the tape. At 3:53 off record.

24 (Whereupon, a short recess was  
25 taken.)

1 THE VIDEOGRAPHER: At 4:03 p.m. on  
2 record.

3 BY MR. SLATER:

4 Q If we look at the temporal -- I'm going  
5 to rephrase the question.

6 Doctor, if we look at the temporal onset  
7 of pelvic and vaginal pain, it followed  
8 immediately after the Prolift was put in Pam  
9 Wicker's body; correct?

10 MR. COMBS: Object to form.

11 THE WITNESS: Correct.

12 BY MR. SLATER:

13 Q By the same token, the hip pain and the  
14 leg length difference had existed for at least  
15 four years before the Prolift surgery, with no  
16 complaints of pelvic or vaginal pain; correct?

17 A Correct.

18 Q Can you point me to any of the articles  
19 listed on either of your list of materials that  
20 we've gone through, any article that supports a  
21 causative link between a hip issue or a leg length  
22 discrepancy and pelvic and vaginal pain?

23 A In the -- there's not a lot in the  
24 literature regarding this, because it, it's more  
25 of a physical therapy/physiatry type of thing, and

1 it's just -- you know, the crossover with gyn is  
2 not necessarily as good as we'd like, but even if  
3 you look at ACOG's chronic pain practice bulletin,  
4 there is a component or a section that talks about  
5 faulty posture issues, you know, being seen and  
6 being an issue in up to, you know, 75 percent of  
7 patients who have, you know, chronic pelvic pain  
8 issues.

9 Q That's only one of the items on your  
10 list of literature that you would say supports  
11 that opinion?

12 A On the -- I mean I, I have additional  
13 literature that would support it. It's not per  
14 se -- I mean there's a whole book on pelvic pain  
15 that talks about these whole issues and  
16 everything. I did not cite it as a specific  
17 literature, because it's the whole darn book that  
18 talks about it, but it does raise all these issues  
19 of body mechanics, gait ambulation issues.

20 It talks about, you know, pelvic floor  
21 muscle dysfunction, it talks about dyspareunia and  
22 stuff, and all of that related to these whole  
23 components. And I will give you -- it's called  
24 "Pelvic Pain," and I don't remember who the author  
25 is, but I mean it's a huge book just on this.

1 It's not something that's easily seen in the  
2 literature per se.

3 There are some other references. I just  
4 can't tell them right off the top of my head.

5 Q My question is this: On the actual  
6 lists of literature that you have served on me,  
7 other than the ACOG practice bulletin dated  
8 March 2004, none of those references you can point  
9 to and say this supports my opinion that the hip  
10 and leg length issue is a cause of the pelvic and  
11 vaginal pain Mrs. Wicker has complained of;  
12 correct?

13 A Probably not on this list.

14 Q Okay.

15 Now, do you have that ACOG practice  
16 bulletin there in the room with you?

17 A Yes, I believe so.

18 Q We should pull it out for a minute.  
19 We'll ask a couple questions about it. I found  
20 this to be interesting reading.

21 A I thought I had it with me, but I seem  
22 to have put it someplace. I've got too many  
23 stacks.

24 All right. Let's just look at it.

25 Okay.

1 Q Do you have it there?

2 A Yes.

3 Q Okay, and just for the record, this is  
4 ACOG practice bulletin number 51, March of 2004.

5 A Yes.

6 Q Correct?

7 A Yes, reaffirmed in 2010.

8 Q This is titled "Chronic Pelvic Pain";  
9 right?

10 A Yes.

11 Q And the reason why you're referring to  
12 this in this case is because you believe Pam  
13 Wicker to have, overall, a reasonable diagnosis  
14 for her chronic pelvic pain; correct?

15 A Yeah, I think that that's probably a  
16 reasonable diagnosis for her.

17 Q Now, if you look at the third page,  
18 which is page 79, there's a table that lists  
19 "non-gynecologic conditions that may cause or  
20 exacerbate chronic pelvic pain by level of  
21 evidence."

22 Do you see that?

23 A Yes.

24 Q Level A evidence would be the highest  
25 level, meaning the most valid?



1           A     That's based on studies that have been  
2     reported, yes, studies that have been done and  
3     reported on that, yeah. I guess yes. I'll just  
4     say that yes, Level A is considered to be better  
5     quality studies.

6           Q     And in essence, in terms of the evidence  
7     supporting inclusion of these different conditions  
8     as potential causes or exacerbating factors for  
9     chronic pelvic pain, the level of evidence --  
10    Level A is the highest, Level B is the next, and C  
11    is the lowest level of quality of evidence;  
12    correct?

13          A     Correct.

14          Q     Now, there's a musculoskeletal column,  
15    and under the Level A evidence it lists "pelvic  
16    floor myalgia, levator ani or piriformis  
17    syndrome."

18                Do you see that?

19          A     Yes.

20          Q     In Mrs. Wicker's case, the first time  
21    that she had indications of or diagnosis of pelvic  
22    floor myalgia was after the Prolift was put in her  
23    body; correct?

24          A     That's the first time she had a clinical  
25    diagnosis of that, yep.

1           Q     The surgeries that she has had performed  
2     to treat her complications from the Prolift, as  
3     well as the inflammatory reaction of her body to  
4     that mesh in her body could cause pelvic floor  
5     myalgia; correct?

6                     MR. COMBS: Object to form.

7                     THE WITNESS: The surgeries  
8     could -- the issue of the inflammatory  
9     reaction, I really think it depends upon, you  
10    know, how much mesh you're talking about.  
11    You're talking about a 2- or 3-millimeter  
12    mesh erosion, I don't think that that's going  
13    to be something that's going to be causing a  
14    pelvic floor myalgia from an inflammatory  
15    reaction that's a 2- or 3-millimeter area.

16    BY MR. SLATER:

17           Q     The distal arms, for example, of the  
18    anterior Prolift system were not completely  
19    removed from Pam Wicker's body and were in there  
20    for years. They could certainly have incited a  
21    continuing chronic foreign body reaction that  
22    could cause myalgia; correct?

23                     MR. COMBS: Object to form.

24                     THE WITNESS: It could.

25

1 BY MR. SLATER:

2 Q Under the musculoskeletal column, under  
3 Level C, the lowest level of evidence, it says  
4 "degenerative joint disease."

5 Do you see that?

6 A I see that.

7 Q It's not specific to any particular area  
8 of the body, as it's stated there; right?

9 A Correct.

10 Q That could, for example, be a reference  
11 to degenerative joint disease within the pelvis  
12 itself; right?

13 A You don't -- well, you can get it in the  
14 hips. You don't get it within the pelvic bone  
15 itself.

16 Q -- get, for example, degeneration of the  
17 sacroiliac joint; right?

18 A You don't usually get degeneration so  
19 much. You get some mobility of the SI joint, but  
20 it doesn't tend to degenerate, per se.

21 Q Are you sure about that? Are you sure  
22 you don't get -- the degeneration of the SI joint  
23 is not a common orthopedic diagnosis?

24 A I think that it -- what I'm saying is in  
25 the patients that I see with these types of

1 things, it is typically more that they have some  
2 hypermobility of the joint. You know, you'd have  
3 to X-ray them to see whether there was any  
4 degenerative changes in the joint.

5 Q You don't hold yourself out as an expert  
6 with regard to degenerative joint disease, do you?

7 A No.

8 Q Okay.

9 Nowhere on this list is there a  
10 reference to hip or leg issues such as we have  
11 with Mrs. Wicker. That's not on this list, is it?

12 MR. COMBS: Object to form.

13 THE WITNESS: I think that's part  
14 of the issue of, that is included in the  
15 faulty or poor posture, that it's -- whether  
16 it's not moving, whatever that would be,  
17 versus whether it is ambulation, it doesn't  
18 necessarily specify it, but there is clearly  
19 literature showing that patients who have  
20 abnormal gait can be more susceptible to some  
21 of these types of pelvic floor issues.

22 I mean she's got sleep  
23 disturbances. I mean she's got a number of  
24 different things that you can sort of check  
25 off on this list as non-gynecologic causes of

1 chronic pelvic pain.

2 BY MR. SLATER:

3 Q And she had all of those conditions  
4 before she had the Prolift and didn't have any  
5 complaints of pelvic or vaginal pain; right?

6 MR. COMBS: Object to form.

7 THE WITNESS: That is correct.

8 BY MR. SLATER:

9 Q As I read this, what I thought they were  
10 ultimately saying in this bulletin is you're going  
11 to see most patients with more than one of these  
12 factors, and if you have a patient who has pelvic  
13 pain due to a gynecologic reason and they also  
14 have non-gynecologic conditions, that just sets  
15 the stage to have worse pain.

16 Am I understanding that correctly?

17 A I think that the combination of two,  
18 gynecologic as well as non-gynecologic, could lead  
19 to more problems of pelvic pain or more difficulty  
20 in treating it, because even if you treat the  
21 gynecologic issue, if the non-gynecologic issue  
22 still remains, the pain is going to continue to  
23 cycle and you're going to continue to have  
24 problems occurring.

25 Q In the case of Mrs. Wicker -- I know

1 we've kind of talked about it, but I want to talk  
2 about it in the context of this bulletin.

3 In Pam Wicker's case, she has a  
4 combination of gynecologic issues that could, in  
5 and of themselves, cause the pelvic and vaginal  
6 pain she has; correct?

7 A They could.

8 Q She also has certain non-gynecologic  
9 issues, such as her hip, her leg length, you said  
10 her sleep, and she has these issues, which you're  
11 saying you believe are contributing to her pain;  
12 correct?

13 A I think that they're -- yeah, they're a  
14 significant contribution to the pain, the  
15 persistence of the pain issues.

16 Q And if I understand correctly, now in  
17 the context of this bulletin as it's boiled down  
18 here, your opinion is: When you put all that  
19 together, that's where you have Pam Wicker.  
20 That's what makes the picture together. When you  
21 put her gynecologic issues related to the Prolift  
22 and her complications and the surgeries related to  
23 that, you put her orthopedic issues together, you  
24 put all that together, and that's how you are able  
25 to answer why Pam Wicker has been where she is and

1     where she is.

2                     Is that accurate?

3                     MR. COMBS: Object to form.

4                     THE WITNESS: I think that that is  
5     accurate that there is probably a  
6     combination, but again, if Prolift was the  
7     major contributing factor or the mesh was the  
8     major contributing factor, you know, you  
9     would -- one would typically expect that  
10    you're going to have, you know, reasonable  
11    complete resolution of the problem as you  
12    take away these different types of meshes.

13                    And yes, I know there's literature  
14    that says that even removal of the mesh may  
15    leave a few fibers here and there, but you're  
16    going to have to -- how are you going to  
17    explain the fact that when she has a mesh  
18    surgery or she has a mesh removal and even if  
19    it's a little bit of granulation tissue of a  
20    couple, you know, millimeters or something,  
21    there is a period of time afterwards, usually  
22    between about 6 to 12 weeks, where she feels  
23    better, and then she begins to have  
24    recurrence of symptoms.

25                    So the question is: The -- if

1           you're talking the chronic inflammation from  
2           the mesh as the only cause of this, the  
3           chronic inflammation from the mesh would have  
4           been ongoing even immediately  
5           postoperatively, and she shouldn't really  
6           have necessarily that improvement, because  
7           you're saying she has still mesh there, she  
8           still has chronic inflammation, and so  
9           therefore she should still have the pain  
10          component there.

11                       So the fact that one of the common  
12          denominators from the time period where she  
13          has surgery until when she experiences  
14          recurrence of the pain very interestingly  
15          coincides with her resuming a significant  
16          amount of her normal activities and her  
17          exercise that, in turn, takes all of these  
18          biomechanical issues that may have been given  
19          an opportunity to sort of rest and not  
20          continue to put demands on the area by her  
21          being less active, you put her into the more  
22          active situation and that begins to trigger  
23          the whole process again.

24                       You're making the assumption that  
25          that retriggering is based on the mesh fibers



1 creating an issue, and in the cases where she  
2 has recurrence of symptoms and there is such  
3 a minor amount of mesh involved, that just  
4 doesn't make logical sense.

5 BY MR. SLATER:

6 Q Let me ask you a couple things, because  
7 I want to go through a few things you said.  
8 Number one -- well, let me ask it this way.

9 Dr. Raz explained that when you operate  
10 this many times on a woman's vagina, and you  
11 continue to dissect the vaginal tissue, you  
12 devascularize the tissue, because you're cutting  
13 blood vessels, et cetera, which weakens the  
14 tissue.

15 Do you agree with that?

16 A Not necessarily. If you had  
17 devascularized tissue, the tissue would be dead  
18 and necrotic and sloughing off.

19 Q Well, you could also devascularize it to  
20 the point where it's not going to be as healthy as  
21 it would be otherwise, but it's not necessarily  
22 dying due to the multiple dissections; right?

23 MR. COMBS: Object to form.

24 THE WITNESS: Yeah, and you could  
25 postulate a whole lot of other things that go

1           into the process as well, but what I'm  
2           doing --

3       BY MR. SLATER:

4           Q       So you and Dr. Raz disagree?

5           A       Yes, and what I'm also basing it on is  
6       the experience in patients who are non-Prolift,  
7       non-mesh patients, and the people who are like  
8       this where there's a mesh, and you can see exactly  
9       the same course of events even in a patient who  
10      doesn't have a mesh or mesh erosion, where there  
11      is this chronic exacerbation and, and improvement  
12      of pain issues based on the ability of her body to  
13      compensate or not compensate for the demands that  
14      are put on her.

15                   So the challenge is: If you were saying  
16      that this was all Prolift and mesh-related, then  
17      what you would have to say is the only people who  
18      develop these kind of problems, et cetera, are  
19      going to have to be those people who have had mesh  
20      and have had Prolift, but what I'm saying, in  
21      clinical practice that is not the case.

22           Q       In Pam Wicker's case, it's more likely  
23      than not that it's a combination of the Prolift  
24      and related issues and these orthopedic and other  
25      non-gynecologic issues?

1           A     I think --

2                         MR. COMBS: Object to form.

3                         THE WITNESS: I think that the  
4           non-gynecologic issues are more contributory  
5           than the gynecologic.

6   BY MR. SLATER:

7           Q     Is, is it your opinion that Pam Wicker  
8           has poor posture?

9           A     They, they use the terminology of  
10    "faulty posture" to describe someone with any type  
11    of asymmetry when they're standing or when they're  
12    sitting, and yes, she has asymmetry when she  
13    stands and when she sits. Her body is not in a  
14    straight alignment.

15          Q     Why is that; because her legs are  
16          different lengths?

17          A     No. It's because of everything that's  
18          going on. She's got it from the shoulder issues,  
19          the cervical issues. She's got it from the pelvic  
20          areas. She's got it from the -- you know, she's  
21          got some -- has had some knee issues in the past.  
22          She's had some coccyx issues in the past from her  
23          fall in 2007.

24                         So, you know, again, if you take the  
25          right side of her body, almost every joint system

1 along that way has had some impact, whether it's  
2 the cervical spine, the shoulder, the hip, the  
3 knee, the broken foot and the coccyx.

4 So, you know, when you have all of that  
5 primarily on, primarily on one side -- I think the  
6 knee was the left side, but, you know, it's going  
7 to have a cumulative effect, even if the patient  
8 doesn't realize that they're sitting differently  
9 or they're standing differently.

10 You know, it, it happens all the time  
11 when we look at a patient and I say you've got --  
12 your right shoulder is higher than your left  
13 shoulder even when you're trying to sit straight,  
14 or this hip is over that hip even when they're  
15 trying to stand straight. That's something we see  
16 quite regularly on a clinical exam, especially in  
17 patients with this type of underlying medical  
18 history.

19 Q Pam Wicker likely has a great deal of  
20 scar tissue within her pelvis both as a reaction  
21 to mesh that was in there and the multiple  
22 surgeries to remove that mesh; correct?

23 MR. COMBS: Object to form.

24 THE WITNESS: I can't make that  
25 statement. At the time that I examined her,

1 she had some thickening at the top of the  
2 vaginal apex which is, quote, scar. It's  
3 also consistent with what you see in a  
4 post-hysterectomy patient. I was not able to  
5 palpate any kind of scar tissue that was in  
6 the lateral areas anteriorly, posteriorly  
7 when I examined her.

8 BY MR. SLATER:

9 Q You could have scar tissue that's not  
10 palpable through the vagina, right, that you  
11 couldn't reach?

12 A I, I guess it's possible, but for it to  
13 be asymptomatic would be pretty uncommon with it  
14 not having some manifestation vaginally.

15 You're trying to say the scar tissue is  
16 bad enough that it's causing her dyspareunia,  
17 which is caused when something pushes against the  
18 vagina, but when I push against the vagina, I  
19 can't palpate the scar tissue, so how is the  
20 pressure against the vagina during intercourse  
21 going to be triggering pain from the scar tissue?

22 Q I didn't say that at all.

23 A Okay.

24 Well, you're saying that if there was  
25 deep scar tissue --

1           Q     Can we go to the next question. Let me  
2 go to the next question. I want to try to get --  
3 I didn't ask another question is the whole point.  
4 It's 4:30. So let me go through a couple other  
5 things with you.

6                     In June of 2012, Mrs. Wicker came home  
7 from a vacation with a bad cough, went to a  
8 medi-center. They, they offered to admit her, and  
9 they said you may have a pulmonary embolism. She  
10 didn't want to be admitted. She signed herself  
11 out and went home.

12                    Is that of any significance to you? Is  
13 that of any significance to you at all to a  
14 reasonable degree of medical probability in  
15 explaining her vaginal or pelvic pain that's at  
16 issue in this case?

17           A     The cough?

18           Q     That episode in June of 2012 when she  
19 had a bad cough, then went to the hospital, to the  
20 medi-center and didn't want to be admitted to an  
21 emergency room to be worked up for a pulmonary  
22 embolism, which it turned out she didn't have, and  
23 the cough went away with antibiotics.

24           A     I think that that's probably not really  
25 a relevant situation here.

1 Q Okay.

2 In Pam Wicker's life she's had some  
3 benign skin lesions removed, either by laser or  
4 freezing of the lesions. Is that of any  
5 significance to you to a reasonable degree of  
6 medical probability with regard to her pelvic or  
7 vaginal issues?

8 A Not -- it depends on what you mean  
9 "issues." It's not -- there's not an association  
10 relative to, if you're talking about her pain or  
11 dyspareunia.

12 Q Right, to the injuries she's claiming,  
13 that's not of any significance; right?

14 A Not to the pain or dyspareunia issues,  
15 yeah, correct.

16 Q Okay.

17 Mrs. Wicker used Retin A for -- and  
18 maybe she still does. I don't remember.

19 That's of no significance to you with  
20 regard to the vaginal or pelvic issues that are at  
21 issue here, is that, if she used Retin A?

22 MR. COMBS: Object to form.

23 THE WITNESS: No, and it would be  
24 simpler if you would just say related to  
25 the -- if you're going to ask that series of

1 questions, related to pelvic pain/  
2 dyspareunia type of things. That way I don't  
3 have to qualify the discussion.

4 BY MR. SLATER:

5 Q Okay.

6 Mrs. Wicker has had injections of  
7 Restylane, R-E-S-T-Y-L-A-N-E, Botox, and  
8 injections of fat for cosmetic purposes.

9 Are, are those injections of any  
10 significance to a reasonable degree of medical  
11 probability with regard to her pelvic or vaginal  
12 issues or dyspareunia?

13 MR. COMBS: Object to form.

14 THE WITNESS: No.

15 BY MR. SLATER:

16 Q In March of 2010, Pam Wicker had rotator  
17 cuff surgery for her shoulder.

18 Do you have an opinion to a reasonable  
19 degree of medical probability that that's somehow  
20 connected to her pelvic and vaginal and  
21 dyspareunia issues?

22 A Yes. I think that's part of the whole  
23 complex about the flares and the improvements  
24 related to when she has either change in her  
25 physical activity level with the exercise, or she



1 has the manifestation of a biomechanical problem.

2 Q In February of 2012, around that time,  
3 Mrs. Wicker had an issue with her ear with some  
4 vestibular problems. She got medication for that,  
5 and apparently it was resolved.

6 Is that of any significance to you to a  
7 reasonable degree of medical probability to her  
8 pelvic or vaginal or dyspareunia issues?

9 A No. Her ear is not related. I will  
10 tell you that.

11 Q Okay.

12 Did you see that Pam actually went and  
13 did research and met with Dr. Newman in California  
14 to explore the potential for stem cell injections  
15 to try to rejuvenate her vaginal tissue?

16 A Yes. I saw that she had met with him on  
17 I think two occasions and that he spoke with her  
18 husband on the phone at one, one occasion.

19 Q The fact that she went and met with this  
20 doctor, never had the treatment, is that something  
21 you're relying on in any way for your opinions in  
22 this case?

23 A No.

24 Q You had said in your supplemental  
25 report -- give me a second.

1           You had said in the second paragraph of  
2   your supplemental report that you wanted to  
3   comment on her saying that she had the need to  
4   stand up to urinate since around 2008.

5           You had commented on that; right?

6           A     Well, that was -- I'm commenting on it,  
7   because that is, if I understand correctly, one of  
8   the potential issues that's related to the  
9   proposed sequelae of her surgery.

10          Q     Was it your point that -- it was your  
11   point that you didn't see any records going back  
12   to '08 or '09 or that time period indicating that  
13   that had never been an issue?

14          A     No. My point was that there are records  
15   stating that this issue -- there's really a lot of  
16   conflicting records talking about this particular  
17   issue. Although she does report at one point  
18   following the surgery that she's having difficulty  
19   with voiding and needs to stand to be able to  
20   void, although she is able to empty her bladder,  
21   that complaint is never evaluated by anyone in  
22   terms of its underlying etiology.

23                There are other times throughout the  
24   record and more specifically in Dr. Raz's record  
25   where he reports no voiding problems. However,

1 then there's other statements where Ms. Wicker is  
2 saying this is still an issue. So there is  
3 conflicting information regarding her potential  
4 voiding complaints of yes, no, yes, no, yes, no,  
5 and no evaluation at this point, so that was my --  
6 that's this reference.

7 Q On page 6 of your main report about Pam  
8 Wicker, you point out that on May 4, 2009 she had  
9 reported that she had to stand up in order to  
10 void, in order to urinate; right?

11 A That was from my review of the records.  
12 That was the first time that it is indicated in  
13 the medical records.

14 Q Okay, and you saw Dr. Raz's testimony in  
15 the transcript where he testified about this and  
16 explained that he thought this was due to her  
17 recurrent prolapse, and the fact that there is  
18 obstruction, and he said at that point he wasn't  
19 comfortable treating that because of the tissue  
20 quality and the repetitive erosions; right?

21 A I saw that he stated that. I disagree  
22 with that, and he has no data to support --

23 Q I didn't ask you if you agree.

24 A I saw --

25 Q I didn't ask you if you agree.

1           A     Okay.

2           Q     So --

3           A     I saw his statement.

4           Q     Okay.

5                     You saw that Dr. Raz testified about the  
6     need by Pam Wicker to stand up in order to  
7     urinate; correct?

8           A     I saw that he -- I'm trying to remember  
9     if I read in his deposition that he said that. I  
10    know in his notes he has said it, but then he's  
11    also said subsequent to his surgeries that she did  
12    not have voiding problems.

13          Q     Well, you understand that she's able to  
14    void; she just has to stand up to do it. You  
15    understand that's what she's reporting; right?

16                     MR. COMBS: Object to form.

17                     THE WITNESS: Yes, but that's  
18    considered by a physician to be a voiding  
19    problem. It's a voiding dysfunction when  
20    you're not able to void in the normal  
21    position.

22    BY MR. SLATER:

23          Q     Okay. Let me ask you this very straight  
24    out.

25                     You met Pam Wicker; right?

1           A     Yes.

2           Q     Spent two hours with her?

3           A     Yes.

4           Q     Did she strike you as somebody who is  
5 going to make it up and say she needs to stand up  
6 to urinate if she really doesn't need to?

7                     MR. COMBS: Object to form.

8                     THE WITNESS: I -- no, I don't  
9 think that she would make it up. I'm just  
10 saying --

11 BY MR. SLATER:

12          Q     So you don't -- so you don't disbelieve  
13 her that she needs to stand up in order to  
14 urinate; right?

15          A     I don't believe her statement that she  
16 makes -- I mean I don't -- double negative. I  
17 don't not believe her statement, if that double  
18 negative makes sense.

19          Q     The, the quadruple negatives that we're  
20 into now.

21                     You agree that -- rephrase. You do  
22 not -- rephrase.

23                     You believe Pam Wicker's report that she  
24 needs to stand up in order to urinate; correct?

25          A     That's what the patient states, and so I

1 would believe that that's what she is  
2 experiencing.

3 Q Okay.

4 A I'm simply saying the medical record  
5 says that she's not complaining of problems, so  
6 that makes it a little more difficult, and since  
7 it was never evaluated, I mean typically if a  
8 problem is a problem enough to the patient that  
9 she voices it or she says this is an issue, then  
10 you're typically going to at least clinically  
11 evaluate it. You may not choose to treat it based  
12 on the risk/benefits of the treatment, but Dr. Raz  
13 hasn't even evaluated it to determine why this is  
14 the issue.

15 Q Dr. Raz actually testified that he did  
16 evaluate and that it's his opinion it's due to the  
17 descent of her bladder that's causing an  
18 obstruction that she needs to stand up in order to  
19 release that so she can let urine flow.

20 Did you see his testimony on that?

21 A I did, but that's totally conjecture.  
22 There is no medical evidence or testing evidence  
23 to support that in any of his record, and there  
24 are actually physiologic -- there's physiologic  
25 information that could actually support

1     alternatively. You know, to say that she has an  
2     obstructed urethra, you are going to need to have  
3     some reason for that obstruction to exist.

4             The cystocele that she has on her MRI is  
5     not of a sufficient degree to cause urinary  
6     obstruction from the urethra. The subsequent  
7     recurrent cystocele that he's talking about that  
8     he doesn't want to treat again is in and of itself  
9     not a sufficient anatomic abnormality to cause  
10    obstruction of the urethra. And he has provided  
11    no -- sorry. You're cutting out, but he has  
12    provided nothing in his evaluation to substantiate  
13    that claim, and it's just not, it's just not  
14    anatomically consistent.

15            Q     -- "I did."

16            A     I'm sorry. You just cut out.

17            Q     I said I move to strike after the first  
18    two words of the answer which is "I did," and then  
19    there was a long explanation. I'm moving to  
20    strike after that first phrase.

21                   Do you have an opinion, Doctor, as to  
22    why it is that Pam Wicker needs to stand up in  
23    order to begin to urinate, in order to urinate?

24            A     I think that there can be a number of  
25    different reasons. I don't think it is from the

1 recurrence of the prolapse. From the -- I'm  
2 trying to remember exactly again, since my brain  
3 is getting a little bit fuzzy at this point, when  
4 was the first report that she said she had to  
5 stand to urinate, whether that was pre-Raz or post  
6 her initial Raz visit.

7 I'm looking here.

8 It sounds like it may have been just  
9 pre- -- yeah, it's pre-Raz, because she's saying  
10 it when she goes into the bladder control center  
11 of Norwalk.

12 So pre-Raz, you know, yes, you could  
13 have spasm in the area, you could have  
14 overcorrection of urethral support from the base  
15 of the Prolift put in too tightly. You can  
16 have -- those would probably be my most likely  
17 situations.

18 I mean the difference between the  
19 standing position and the sitting position is  
20 usually the sitting position is going to put a  
21 little more anterior pull or elevation of the  
22 urethra, and he talks -- Dr. Raz talks about the  
23 fact that she did not have a hypermobile urethra,  
24 so it is certainly possible that that urethra was  
25 perhaps over-elevated at the time of the original



1 surgery.

2                   However, then subsequent to that time,  
3 you've also got Dr. Raz going in and putting in  
4 his plication sutures around the urethra. We  
5 talked about in one of the operative notes where  
6 he was putting Vicryl sutures and supporting  
7 underneath the urethra. We went back and forth  
8 with that. That can certainly exacerbate some of  
9 the voiding complaints.

10                   Yes, it was there beforehand. Does it  
11 persist because of the original problems? Does it  
12 persist because new issues come in as other things  
13 fight? I mean I can't totally tell you that,  
14 because nobody has evaluated this patient. Nobody  
15 has done, you know, a basic uroflow study on the  
16 patient or anything that would look for a, quote,  
17 "obstructive" phenomenon.

18           Q       The orthopedic and, quote-unquote,  
19 "postural" issues that you've talked about -- I'll  
20 start over.

21                   With regard to the orthopedic and  
22 postural issues with her hip, her leg, her  
23 shoulder, those issues together, do I understand  
24 correctly that you believe those issues are  
25 leading to pelvic floor muscle spasm, which is

1 leading to the pelvic pain and dyspareunia, that  
2 that's, that's how they're contributing to that?

3 A I think that that's a significant  
4 component based on my examination and the areas  
5 where she was reporting the discomfort and  
6 tenderness.

7 Now, in her most recent deposition, she  
8 stated, made a comment about the fact that she was  
9 experiencing more introital dyspareunia rather  
10 than the deep penetration dyspareunia that she has  
11 talked about from all the previous times.

12 The explanation for why she has the  
13 introital dyspareunia, first of all, that's not  
14 really going to be Prolift-related, really, in any  
15 way I can think of, and there's not really --  
16 based on my clinical examination, her introitus in  
17 the area was totally normal. So I can't tell you  
18 if she's now experiencing introital versus deep  
19 penetration dyspareunia. You know, we've got  
20 other factors coming into play.

21 Q My question ultimately is: Pam Wicker's  
22 pelvic pain, her vaginal pain, you believe is  
23 being caused primarily by pelvic floor muscle  
24 spasm?

25 A Yes. Certainly at the current time,

1     yes.

2             Q     When Pam Wicker was deposed the other  
3     day and you saw her saying that she feels pain on  
4     penetration towards the front of the vagina and  
5     not just the -- well, rephrase.

6             The testimony that you're referring to  
7     where Pam Wicker said she feels discomfort at the  
8     introitus, she never said she doesn't feel it on  
9     deep penetration, did she?

10            MR. COMBS:   Object to form.

11            THE WITNESS:   I don't remember  
12            whether she specifically talked about that,  
13            but she did talk about a new or different  
14            aspect, an additional aspect in this  
15            particular deposition that was not raised  
16            previously in any of the medical records  
17            and/or at least in my evaluation.

18     BY MR. SLATER:

19            Q     In fact -- tell me if I'm wrong, or if  
20     you don't know, you don't know or don't  
21     remember -- she wasn't asked whether she still  
22     feels discomfort if she attempts deep penetration.

23            A     As I said, I don't remember the topic of  
24     deep penetration specifically being discussed in  
25     the most recent deposition, but I know --

1 Q Let me ask you this.

2 I'm sorry. Go ahead.

3 A I was saying but I do know that there  
4 was the more upon, you know, entry kind of pain.  
5 I remember seeing that and specifically noting  
6 that, because it was a different statement than or  
7 a different kind of complaint than she had had  
8 previously.

9 Q Is one of your opinions that Pam Wicker  
10 should not exercise?

11 A I think that she needs to make some  
12 significant changes in how she makes demands on  
13 her body. I think that some of the changes that  
14 she has stated she's made more recently, some of  
15 the yoga type of situations, some of the more  
16 stretching type of work and perhaps less of the  
17 weight-bearing type of exercise, I think those are  
18 potentially better choices for her.

19 You know, people like this, one of the  
20 things we talk about is even swimming. It's not  
21 that she can't exercise. It's that doing certain  
22 exercises places increased demand on structures,  
23 joints, muscles, et cetera, and so if those  
24 muscles, bones, joints, et cetera, are  
25 compromised, then you may have to adapt.

1           Just like, you know, you got a bad knee,  
2    you may stop running, but you might start -- I  
3    don't know -- something else, you know. It's just  
4    there are adaptations that sometimes have to be  
5    made, and what you choose or your form of exercise  
6    you choose based on the wear and tear on your  
7    body, and that is sometimes difficult to accept,  
8    but the tradeoff is: If you continue to do this,  
9    you're going to continue to exacerbate that. If  
10   you want that to go away, then you have to make a  
11   change in this.

12           Q     Move to strike.

13                   When Mrs. Wicker has not been feeling  
14   significant pain, she has been honest with her  
15   doctors and told them that; right?

16           A     There are, there are comments in the  
17   medical record where she says she is feeling a  
18   little bit better or -- Raz is especially saying,  
19   quote, "doing well," although there are other  
20   comments that say she's still having an issue. I  
21   have not seen any comments in the records where  
22   she's come in and she's, you know, reporting that  
23   she's, you know, without pain, doing her normal  
24   activities and without pain.

25           Q     So just coming back to my question, when

1 Pam Wicker has reported when she was feeling  
2 better and having better days and better periods  
3 of time, she has been honest with her doctors and  
4 told them that; right?

5 MR. COMBS: Object to form.

6 THE WITNESS: I mean I assume that  
7 she's being honest with her doctors  
8 throughout the time period. So I assume that  
9 yes, that's the case.

10 BY MR. SLATER:

11 Q The scar at the apex of her vagina that  
12 you found on your exam, what do you attribute that  
13 to?

14 A Surgery. I mean a hysterectomy alone,  
15 hysterectomy alone can cause -- you're going to  
16 see an apical incision and you're going to see a,  
17 quote, apical scar. The vaginal cuff that we talk  
18 about, that's going to be less distensible than  
19 the surrounding tissue.

20 I think that this is probably not just  
21 hysterectomy-oriented, because the scar, I guess  
22 for a better word, does end up being a little bit  
23 on the vertical side, not just horizontal. If you  
24 are just after hysterectomy, you usually see it  
25 just a horizontal, so it's probably -- it's the

1 pelvic surgery she's had. I can't tell you which  
2 one caused it.

3 Q You're talking about the subsequent  
4 surgeries following from the Prolift surgery?

5 A From the hysterectomy to the Prolift  
6 surgery to the subsequent repeat surgeries, I  
7 can't tell you which one is causing that.

8 Can I go off the record for just a  
9 second, please.

10 Q Sure.

11 THE VIDEOGRAPHER: Off record at  
12 4:49.

13 (Whereupon, a short recess was  
14 taken.)

15 THE VIDEOGRAPHER: At 4:56, on  
16 record.

17 BY MR. SLATER:

18 Q Doctor, when you did your exam, you  
19 found the vaginal length to be 6 centimeters to  
20 the left side and 6.5 centimeters to the right.

21 That would be a shortened vaginal  
22 length; correct?

23 A Yes.

24 Q You point out that the right side of the  
25 vaginal apex was "more distensible."

1                   What does that mean?

2           A       That means that there was more give of  
3   the tissue, more pliability to the tissue so that  
4   I could push from -- let's say the  
5   6.5 centimeters, if I pushed on that area, it  
6   would, it would allow the vagina to go a little  
7   bit deeper, because there was more give in that  
8   area, as opposed to the other side that had less  
9   give of the tissue.

10          Q       And why do you think one side had less  
11   give, in this case, the left side?

12          A       Because she has more scarring in that  
13   side than she does on the other.

14          Q       So based on your opinion, you certainly  
15   were able to confirm that there is scarring of her  
16   vagina; correct?

17          A       Yeah, I mean this is, it's, it is  
18   similar to what you will see in patients who have  
19   had any type of vaginal surgery.

20          Q       Well, the only type that Pam Wicker had  
21   was Prolift surgery; right?

22          A       I understand, but I'm saying that her  
23   exam at the apex of the vagina with the way the  
24   tissue gives a little more on one side versus  
25   another side is consistent with anyone who has



1     undergone a vaginal surgery, regardless of the  
2     procedure.

3           Q     Well, Pam Wicker has had, if you include  
4     the Prolift, six vaginal surgeries since  
5     October 2008; right?

6                     MR. COMBS:   Object to form.

7                     THE WITNESS:  I believe that's how  
8     many I counted, yes, and you can see this  
9     after six.  You can see it after one.  I  
10    actually was impressed that her vagina was in  
11    as good a shape as it was, considering the  
12    number of surgeries she had had.

13  BY MR. SLATER:

14           Q     Let me go through this a little bit.  
15     Pam Wicker has vaginal scarring; correct?  You  
16     confirm that on your exam; right?

17           A     She has an area of a scar.  She has an  
18     area of less distensible tissue.  If you want to  
19     use the word "scar" for that, that's fine.

20           Q     And that's on the left side of the  
21     vertical cuff scar?

22           A     It's on -- no, it's on the left -- it's  
23     on the left side of the horizontal plane --

24           Q     Okay.

25           A     -- of the vaginal cuff.

1           Q     When you applied pressure with your  
2     finger against the vaginal cuff, Mrs. Wicker  
3     complained of tenderness along the scar; correct?

4           A     I'm just looking here back at my notes  
5     here.

6           Q     To the top of 17 of your report.

7           A     Thank you. I'm just looking at my  
8     original comments here.

9                     It did reveal some tenderness along in  
10    the midline along that vertical area, not along  
11    the horizontal area that we just talked about.

12          Q     You found a tenderness when you palpated  
13    with your finger the lateral aspects of the vagina  
14    over the pelvic floor muscles; correct?

15          A     Correct.

16          Q     And then you say -- rephrase.

17                     "In the supine position, there was mild  
18    tenderness along the right obturator internus  
19    muscle."

20                     That was another finding you made on  
21    your exam; right?

22          A     Correct.

23          Q     You found increased tone and mild  
24    tenderness of the left mid-pubococcygeus muscle;  
25    correct?

1           A       Yes.

2           Q       And when we're talking about these  
3       findings in the lateral aspects over the pelvic  
4       floor muscles and the findings in the supine  
5       position, you're talking about tenderness that you  
6       believe is due to pelvic floor myalgia?

7                   MR. COMBS: Object to form.

8                   THE WITNESS: Again, I don't  
9       typically use "myalgia" as a terminology, but  
10      tenderness due to the pelvic muscle,  
11      increased tone and sensitivity, I guess.

12      BY MR. SLATER:

13          Q       And do you have an opinion as to why you  
14      believe that Mrs. Wicker continues to be tender  
15      over the midline scar at the vaginal cuff?

16                  MR. COMBS: Objection.

17      BY MR. SLATER:

18          Q       Why that tenderness has not gone away?

19          A       Because that's what you sometimes see at  
20      the vaginal cuff in a patient who's had one or  
21      perhaps more than one surgery, and we don't always  
22      know why that occurs, whereas someone else can  
23      have exactly the same anatomy and not be tender.

24          Q       Based on your POP-Q measurements, what  
25      would you say is the status at the time of your

1 exam of Pam Wicker's prolapse?

2 A In the standing position she has some  
3 mild anterior wall relaxation, and she has some  
4 slight descent of her vaginal cuff. That's going  
5 to be the position where the majority of the, you  
6 know, the pressure is going to be. She does not  
7 appear to have really anything going on with the  
8 posterior wall, and her vaginal opening appears to  
9 be of normal diameter.

10 Q If you had to stage or grade the  
11 cystocele, what would you say that is?

12 A I'd probably call it, for me, a stage 2.

13 Q You saw the records of the physical  
14 therapist, Heather Strauch, S-T-R-A-U-C-H;  
15 correct?

16 A Yes, I did see her records. Some of  
17 them were a little difficult to read based on the  
18 Xerox copy and the handwriting, but yes.

19 Q Did you read her deposition?

20 A I -- even though it says I theoretically  
21 received it, I don't recall having received it, so  
22 no, I did not read her deposition.

23 Q You note in your report on page 20 that  
24 on July 26, 2012, Heather Strauch noted "right  
25 coccygeus tenderness, left obturator severely

1 tender, palpable scar tissue left posterior  
2 superior vaginal vault, and palpable solid mesh  
3 left urethral tissue"; correct?

4 A Hang on two seconds. Let me get the  
5 original.

6 (Discussion held off the record.)

7 THE WITNESS: What is the date of  
8 the exam?

9 BY MR. SLATER:

10 Q On page 20 of your report --

11 A Yes.

12 Q -- you refer to the last exam, the last  
13 treatment on July 26, 2012.

14 A Sorry. My copy that I printed out last  
15 night doesn't have pages on it.

16 MR. COMBS: It's near the end.

17 THE WITNESS: I'm sorry. I'm  
18 getting a little fried, so . . .

19 Thank you. I'm glad somebody could  
20 find it. Ah. On June 13, 2012. All right.  
21 There is one note I have from -- yeah, the  
22 July 26. Okay.

23 So which one are we talking about?

24 Which visit?

25

1 BY MR. SLATER:

2 Q On July 26 Heather Strauch confirmed  
3 that she found on that exam and her treatment  
4 right coccygeus tenderness?

5 A Correct.

6 Q Left obturator severely tender?

7 A Correct.

8 Q Palpable scar tissue left posterior  
9 superior vaginal vault?

10 A Hang on.

11 Q And palpable solid mesh, left urethral  
12 tissue.

13 You documented that in your report;  
14 right?

15 A Yes. That's what she's stating she  
16 palpated. I mean I examined her subsequent to  
17 that time, and I did not feel anything  
18 suburethrally that I would consider to be mesh.  
19 Other than that --

20 Q Move to strike after "palpated."

21 A couple pages later you talk about --

22 A Can you just hold it for just a second,  
23 please.

24 Okay. Thank you.

25 Q Two pages later, middle of the page,

1     talking about your exam, you say "while the  
2     interior -- anterior" -- rephrase.

3                 You say that "while the anterior vaginal  
4     wall showed evidence of thinning consistent with  
5     her lower anterior wall support defect, what are  
6     you talking about there, the thinning?

7             A     I used that term to describe vaginal  
8     tissue that has lost its rugae, lost the quality  
9     of typically a pre-menopausal patient, or it  
10    has -- or patients can have that sometimes if they  
11    have had, you know, a significant prolapse more so  
12    than usually hers, where it has taken the rugae  
13    and just basically stretched it out like  
14    corrugated cardboard, just being flattened out  
15    like that.

16                THE VIDEOGRAPHER: We've got two  
17     minutes on this tape.

18                THE WITNESS: Do you have an  
19     estimate of about how much more time you're  
20     going to want?

21                MR. SLATER: Not much longer. 20  
22     minutes maybe.

23                THE WITNESS: Otherwise, we're  
24     going to start getting to a point of needing  
25     a second time.

1 MR. SLATER: Why don't we do this?  
2 Why don't we change the tape? I really don't  
3 think I have much left. I mean I'm hoping to  
4 be done in 15 minutes or so.

5 THE VIDEOGRAPHER: At 5:09 we're  
6 going off the record in the continuing  
7 deposition of Dr. Horbach.

8 (Whereupon, a short recess was  
9 taken.)

10 THE VIDEOGRAPHER: Our time now is  
11 5:11 p.m., and we're on record beginning  
12 disc 4 in our continuing deposition of  
13 Dr. Nicolette Horbach.

14 BY MR. SLATER:

15 Q Doctor, one of the things you say in  
16 your report is that when Dr. Raz attempted to  
17 elongate Mrs. Wicker's vagina, that he could have  
18 "altered the amount of tension on the Prolift mesh  
19 arms and increased the likelihood of subsequent  
20 scarring and mesh erosion and perpetuating the  
21 need for further surgery."

22 Do you believe to a reasonable degree of  
23 medical probability that likely occurred?

24 A Yeah, I think that there is, that his  
25 choice of how he approached the procedure did



1 contribute to additional problems for her related  
2 to the Prolift and the need for more surgery.

3 Q You would agree with me that Pam Wicker  
4 still has a risk of having more mesh erosions in  
5 her life; right?

6 A I, I don't -- I'm trying to recall.  
7 There was one ultrasound that Raz did showing some  
8 mesh in the suburethral area, although I think  
9 that was the first initial ultrasound that he did.

10 If that's the case, at the present time  
11 I certainly can't feel any additional mesh that  
12 would be present that would be likely to come to  
13 the surface, and we don't have any subsequent or  
14 recent ultrasounds to indicate that there is still  
15 residual mesh, if I'm recalling when that  
16 ultrasound was done.

17 Q It's possible for mesh that was not seen  
18 on those ultrasounds, just due to normal movement,  
19 mechanical forces in the pelvis to migrate; right?

20 MR. COMBS: Object to form.

21 THE WITNESS: If he's, if he's  
22 putting forward, and if you believe that the  
23 ultrasound is a highly diagnostic tool to  
24 find mesh that you can't necessarily palpate  
25 even, if the ultrasound doesn't find mesh,

1           then the likelihood that that's superficial  
2           enough or even there's something there that's  
3           going to come to the surface I think is not  
4           present, I think.

5       BY MR. SLATER:

6           Q     You don't believe that an ultrasound  
7           shows all of the mesh in the pelvis? You don't  
8           believe that to be so; right?

9           A     Why would you say that?

10          Q     Because I think you probably don't. I  
11          think most people would say it wouldn't show all  
12          the mesh. I mean I've spoken to doctors who use  
13          this exact technology who have told me that it's  
14          not going to show you every bit of mesh. It's the  
15          best technology available to image mesh in the  
16          pelvis, but it's not 100 percent.

17                       MR. COMBS: Object to form.

18       BY MR. SLATER:

19          Q     I'll ask the question clean, because it  
20          had a little bit of my commentary in it.

21                       Doctor, have you ever studied the  
22          question of whether or not ultrasound of the type  
23          Dr. Raz utilized would be expected to show  
24          100 percent of the mesh within the pelvis?

25          A     I have not studied that, but again, the

1     hard part is --

2             Q     That was my question, though. I just  
3     asked if you studied it.

4             A     I have not studied that.

5                     MR. SLATER: I'm going to check  
6     some of my notes. I think I may be done.

7                     Well, while I'm looking at my  
8     notes, let's do this. We've marked as  
9     Exhibits 6 through 12 Dr. Horbach's  
10    handwritten notes. I would just ask you,  
11    Doctor, for the record to just go through  
12    them, 6 through 12, exhibit by exhibit, and  
13    just in very simple terms, just tell us what  
14    each exhibit is so we have that for the  
15    record, and I'll check my notes while you're  
16    doing it.

17                     (Discussion was held off the  
18    record.)

19                     THE VIDEOGRAPHER: At 5:17 off  
20    record.

21                     (Whereupon, a short recess was  
22    taken.)

23                     THE VIDEOGRAPHER: Now 5:18 on  
24    record.

25                     THE WITNESS: So in reviewing the

1 exhibits that you've asked, that have been  
2 marked, Exhibit 6 represents my handwritten  
3 questions and the answers of Ms. Wicker at  
4 the time I did her IME exam, as well as my  
5 handwritten notes of the physical findings at  
6 the time that I did her examination per se.  
7 Not -- I did not ask every question that I  
8 had pre laid out here, but there's questions  
9 that I planned to ask her as well as answers.

10 Exhibit 7 are notes that are a  
11 summary of comments during depositions of  
12 Dr. Raz, Ms. Wallace, Dena Harris and  
13 Dr. Moldwin.

14 Exhibit 8 is a list of essentially  
15 chronologically of medical surgeries and  
16 procedures as well as chronologic history of  
17 how different symptoms were presenting from  
18 early gynecologic history going through to  
19 2009, as well as notes that I've taken  
20 regarding new medical records that were  
21 provided to me of visits after my IME.

22 Exhibit 9 again is a summary of  
23 medical history, pertinent issues that I  
24 found in different systems, and in -- listed  
25 chronologically.

1                   Exhibit 10 is a summary of my notes  
2                   when I did the original medical review. It  
3                   includes Bercik records, Raz records,  
4                   orthopedic records, primary care, gyn  
5                   records, so that's a summary for me to  
6                   review.

7                   Exhibit 11 is a summary for myself  
8                   of some of the different issues that I think  
9                   are going on and information substantiating  
10                  that or not from the medical record.

11                  And Exhibit 12 is a summary of the  
12                  patient's pharmacy records and when she's had  
13                  medications filled and which medications,  
14                  which doctor, over a multiple-year history of  
15                  time.

16                  And that's it.

17                  MR. SLATER: I have no other  
18                  questions.

19                  MR. COMBS: Let's take about a  
20                  five-minute break, and then I will do a brief  
21                  redirect and see if we can finish.

22                  MR. SLATER: Let me just  
23                  understand. I didn't know you were going to  
24                  do that. I mean I'm trying to stop for  
25                  Dr. Horbach's benefit. If you've got more

1           time, I could ask more questions. I have  
2           three articles here I could question about  
3           for a while.

4                   MR. COMBS: Well, I mean of course  
5           I'm going to ask some questions. You can't  
6           say, oh, you don't get to ask any questions  
7           because I want to stop. I mean I have some  
8           questions I'm going to ask.

9                   MR. SLATER: For hours.

10                  MR. COMBS: I don't plan on being  
11           here for hours, but, you know . . .

12                  MR. SLATER: Well, I'm going to  
13           reserve my right, if this become a lengthy  
14           redirect, to resume my questions, because I'm  
15           trying to be courteous, and if counsel  
16           thinks, you know, is going to ask a lot of  
17           questions, then I'm going to resume.

18                  THE WITNESS: If it goes on too  
19           long, I'm going to request that we set up,  
20           you know, another time.

21                  THE VIDEOGRAPHER: I have 5:23 off  
22           record.

23                   (Whereupon, a short recess was  
24           taken.)

25                  THE VIDEOGRAPHER: It is now

1 5:33 p.m., on record.

2 EXAMINATION BY COUNSEL FOR DEFENDANTS

3 BY MR. COMBS:

4 Q Dr. Horbach, I have some brief questions  
5 for you.

6 Do you remember when Mr. Slater asked  
7 you questions regarding the pathology work of  
8 Drs. Klinge and Klosterhoff?

9 A Yes.

10 Q Are you aware of any literature that  
11 clinically correlates their hypothesis to outcomes  
12 in actual patients?

13 A No. I'm not aware of any literature  
14 that compares good and bad outcomes in patients,  
15 based on explants and the pathology seen in  
16 explants relative to the mesh or pore size.

17 Q Same question on their theory about  
18 average porosity. Are you aware of any literature  
19 that correlates their theory to clinical outcomes  
20 in actual patients?

21 A No. I'm not aware of any literature  
22 that looks at comparisons of clinical outcomes  
23 from good outcomes or bad outcomes and compares  
24 the porosity -- I think that's what you were  
25 asking me -- of the mesh.

1           Q     Dr. Horbach, Mr. Slater asked you  
2     questions about review of internal company  
3     documents. Why is it that you did not ask to  
4     review additional internal company documents?

5           A     I did not review the internal documents,  
6     as I perceived my role as a clinical expert to  
7     provide an opinion based on the clinical  
8     management of prolapse, the surgery itself, the  
9     management of a patient similar to Mrs. Wicker,  
10    and that I am not an expert of the internal  
11    regulatory or commercial requirements that are  
12    necessary for companies to make decisions  
13    regarding their activities.

14          Q     Now, you testified that you view your  
15    role as providing clinical expertise. Would that  
16    include a review of the medical records?

17          A     Yes, that would include a review of the  
18    medical records.

19          Q     And did you review all of the medical  
20    records in this case?

21          A     I did.

22          Q     And would applying clinical expertise  
23    include a review of the medical literature?

24          A     Yes, it would.

25          Q     And have you reviewed all of the



1 articles that are set forth on the lists that were  
2 introduced by Mr. Slater as Exhibits 4 and 5?

3 A I have reviewed and read all that  
4 literature at one point or another in my  
5 evaluation of this particular case.

6 Q Mr. Slater asked you questions about the  
7 July 2009 article that your practice group  
8 published.

9 Do you remember those questions?

10 A I don't remember the questions, but I  
11 remember he asked me about it.

12 Q Did that article identify any new risks  
13 related to pelvic floor or mesh surgery?

14 MR. SLATER: Objection to the form.

15 THE WITNESS: The -- our article  
16 that was published in 2009 did not identify a  
17 new risk in, for pelvic surgery or actually  
18 for any surgery. It identified that -- no,  
19 let me back up.

20 We, as surgeons, realize that pain  
21 is a consequence of any surgery we do,  
22 whether it's in, you know, orthopedics or the  
23 leg or your gall bladder or a hysterectomy or  
24 a pelvic floor repair. We have data that  
25 supports that patients, even

1 post-hysterectomy, will have -- a certain  
2 percentage will develop pain over a period of  
3 time that may not be amenable to treatment.

4 I think the article, from our  
5 perspective as clinicians, helped us to try  
6 to determine whether there was a group of  
7 patients that were more susceptible to  
8 developing these conditions.

9 Was there some clinical factor that  
10 we could identify that would make the patient  
11 more susceptible to developing these  
12 conditions, and if so, you know, that we  
13 needed to look for that in all of our  
14 patients, which it changed, again, that  
15 preoperative evaluation and preoperative  
16 counseling and/or preoperative preparation  
17 for surgery, but it also changed it not just  
18 for whether it was a Prolift surgery or not.  
19 It changed it across the board for all of the  
20 surgeries that we do for our patients,  
21 whether it's laparoscopic, abdominal, native  
22 tissue, mesh, you know, hysterectomy.

23 It requires -- it alerted us to  
24 screen for that in all of these types of  
25 patients by trying to find clinical

1 correlates for who might be at more risk.

2 (Exhibit 21 was marked for  
3 identification.)

4 BY MR. COMBS:

5 Q I'm going to mark as Exhibit 21 the ACOG  
6 practice bulletin that you questioned Dr. Horbach  
7 on, the March 2004.

8 Dr. Horbach, is this the ACOG practice  
9 bulletin that you were questioned about?

10 A Yes. It's bulletin 51 that was  
11 originally written in 2004 and then, as noted, was  
12 reaffirmed in 2010, which, per ACOG, means that  
13 they re-reviewed it and either made potential  
14 changes or just said this is fine the way it is.

15 Q And was this one of the factors on which  
16 you based your opinion regarding Mrs. Wicker's  
17 musculoskeletal issues contributing to her current  
18 condition?

19 MR. SLATER: Objection.

20 THE WITNESS: It was one of the  
21 factors, but in reality it's, it's to some  
22 extent a minor factor. The question of give  
23 me literature to show that these things are  
24 going on, sometimes our understanding of  
25 problems and our recognition of problems and

1           our communication of problems among ourselves  
2           way precedes things appearing in the  
3           literature.

4                       And so this was an attempt to at  
5           least say yes, this has been -- you know,  
6           this is, this musculoskeletal issue, the  
7           orthopedics, the biomechanics is not just  
8           something that is pulled out of the air, that  
9           this is something that has been recognized as  
10          part of the pelvic pain syndrome or  
11          situation, and also to reiterate that  
12          dyspareunia is viewed as a subset of pelvic  
13          pain.

14   BY MR. COMBS:

15           Q       And did this article in regard to --  
16          well, strike that.

17                       Did this practice bulletin in regard to  
18          musculoskeletal disorders conclude that "faulty  
19          posture in particular and exaggerated lumbar  
20          lordosis and thoracic kyphosis, called typical  
21          pelvic pain posture, may account for up to  
22          75 percent of cases of chronic pelvic pain"?

23           A       That is a statement that is made in the  
24          bulletin based on a reference from, you know,  
25          other articles, and it is ACOG's comments in the

1     bulletin to highlight that musculoskeletal  
2     disorders may be a one of the etiologies for  
3     pelvic pain.

4             Q     Dr. Horbach, I want to ask you a  
5     question about the procedure that Dr. Raz used  
6     on -- I believe it's the July 9, 2009 surgery, the  
7     suture net.

8             A     Yes.

9             Q     Are you aware of any randomized  
10    controlled trials that address the safety or  
11    efficacy of that procedure?

12            A     No. I am not aware of any randomized  
13    controlled trials. There -- the procedure is  
14    described in the literature in 2011 in an article  
15    that was I think written in Current Urology, where  
16    it describes what he calls the CRISP, C-R-I-S-P,  
17    procedure, which is a procedure that he had  
18    devised in an attempt to treat cystocele.

19                   There was no data about randomized  
20    trials being performed prior to that procedure  
21    being used. He does make a comment in that, in  
22    this particular article that there are  
23    complications, but, quote, "early treatable  
24    complications such as exposed 2 to 3 millimeters  
25    of suture can be ideally treated in the office."

1 Q And that article was from 2011?

2 A Correct.

3 Q And in that article does Dr. Raz state  
4 that long-term data is still needed on this  
5 procedure?

6 A Yes, he does. Unfortunately, he's got  
7 several, multiple articles in the literature about  
8 different procedures that he has developed over  
9 the years with somewhat short follow-up but yet  
10 advocating those procedures.

11 Q Dr. Horbach, Mr. Slater asked you a  
12 number of questions about the onset of  
13 Mrs. Wicker's pelvic pain, and, in all those  
14 questions, stated to you that the onset occurred  
15 at the time of the Prolift surgery. Now I want to  
16 ask you some follow-up questions about that.

17 Now, did Mrs. Wicker's gynecological or  
18 urogynecological condition change prior to the  
19 Prolift surgery?

20 A Yes. I mean she had presented to both  
21 her regular gynecologist and subsequently referred  
22 to Dr. Bercik because of symptoms related to  
23 pelvic relaxation with both a bulge that she was  
24 aware of as well as complaints of pelvic pain that  
25 was referred to in the medical record by

1 Dr. Bercik in his first visit with her.

2 Q And would that include the evidence in  
3 the medical record that you and Mr. Slater  
4 discussed earlier today about references to pelvic  
5 pain prior to the Prolift procedure?

6 MR. SLATER: Objection.

7 THE WITNESS: Yes. I think in my  
8 comments previously about pelvic pain not  
9 being present prior -- or prior to the  
10 Prolift procedure, I think I was focused more  
11 on our discussion about the musculoskeletal  
12 levator issues, et cetera, and really focused  
13 on that, that we didn't necessarily have  
14 proof that she was having pain from that  
15 muscular issue, even though I had neglected  
16 to include that she was reported to have  
17 pelvic pain at least for a period of time  
18 prior to her Prolift procedure.

19 BY MR. COMBS:

20 Q And in that procedure did Mrs. Wicker  
21 also have a number of concomitant procedures as  
22 well?

23 A In addition to the Prolift, yes.

24 Q Yes, ma'am.

25 A She did.

1 Q And was one of those a vaginal  
2 hysterectomy?

3 A It was.

4 Q Now, Mr. Slater asked you a number of  
5 questions about Mrs. Wicker's vaginal length, and  
6 is a shortened vaginal length a known complication  
7 of a vaginal hysterectomy?

8 MR. SLATER: Objection.

9 THE WITNESS: A shortened vaginal  
10 length is a known complication of a vaginal  
11 hysterectomy, yes.

12 BY MR. COMBS:

13 Q Dr. Horbach, earlier today Mr. Slater  
14 asked you questions about the risk/benefit  
15 information conveyed by the IFU.

16 Do you remember those questions?

17 A Yes. We did discuss the IFU briefly.

18 Q And is it your opinion that the IFU is  
19 adequate to convey the risks and benefits of the  
20 Prolift procedure to pelvic surgeons?

21 MR. SLATER: Objection. What's the  
22 point of this? Objection.

23 THE WITNESS: It is my opinion that  
24 the information provided in the IFU does  
25 provide appropriate warning when taken into



1 context with the experience and training of  
2 pelvic surgeons and especially pelvic  
3 surgeons who are involved with using  
4 reconstructive materials, such as synthetic  
5 meshes.

6 BY MR. COMBS:

7 Q And just as Mr. Slater said that he  
8 would ask if you could rely on your answers in the  
9 Schubert deposition to shorten this deposition,  
10 I'm going to ask you the same question about the  
11 IFU.

12 You were asked a number of questions  
13 about the IFU in the Schubert deposition.

14 Do you remember that?

15 A I think so. At this point I'm hoping  
16 so, yes.

17 Q And would your answers here be the same?

18 A Yes. I think that one of the, one of  
19 the issues with the IFU is the IFU has to be taken  
20 into context with the overall spectrum, as I  
21 mentioned, of experience, training of a pelvic  
22 surgeon. The IFU is not designed to be a  
23 substitute for clinical training or the single  
24 source of clinical training for someone who is  
25 doing a prolapse surgery or certainly a prolapse

1 surgery with or without the mesh.

2 In many cases physicians don't even read  
3 the IFUs or look at them any more than they do  
4 when you get your warning thing from your  
5 prescription that you fill at the pharmacy and you  
6 toss that perhaps in the trash.

7 So it is -- the information that is  
8 conveyed is not information in isolation. It's a  
9 part of the totality, and whether you're using  
10 mesh in a Prolift or whether you're using mesh in  
11 a sacrocolpopexy or any other type of procedure,  
12 those same risks apply.

13 Q And is it your opinion to a reasonable  
14 degree of medical probability that the  
15 complications that Mrs. Wicker alleges in this  
16 case are complications that were warned of in the  
17 IFU?

18 MR. SLATER: Objection.

19 You can answer.

20 THE WITNESS: I believe they were,  
21 based on the complications related to mesh  
22 surgeries and prolapse surgeries in general.  
23 All surgeons know that the complications that  
24 she experienced are complications that can  
25 happen with any prolapse surgery and any

1 prolapse surgery including mesh.

2 BY MR. COMBS:

3 Q Dr. Horbach, Mr. Slater asked you some  
4 questions about whether a number of cosmetic  
5 procedures contributed to Mrs. Wicker's pelvic  
6 pain or dyspareunia.

7 Do you remember those questions?

8 A Yes.

9 Q Now, it was your testimony in general --  
10 and I'm paraphrasing -- that those cosmetic  
11 procedures did not contribute to her pelvic pain  
12 or her dyspareunia; is that correct?

13 A That's correct.

14 Q Now, does that mean that those  
15 procedures are irrelevant to any of the analysis  
16 that you've done in this case?

17 MR. SLATER: Objection. Improper  
18 question.

19 You can answer.

20 THE WITNESS: No. I think that  
21 the, the totality again of her medical record  
22 and the fact that she has undergone multiple  
23 surgical procedures prior to the Prolift,  
24 including cosmetic and/or otherwise, as well  
25 as has had an experience over the years with

1 her children undergoing surgical procedures  
2 means that this is not a patient who is a --  
3 I hate to say "virgin" for surgery, but is  
4 not -- this is not the first time she's  
5 undergone a surgical procedure or the first  
6 time she's seen a consent form or the first  
7 time that she has been counseled regarding  
8 the risks and benefits of a surgery and may  
9 still elect to go ahead for the surgery, and  
10 has chosen in the past to do procedures or do  
11 surgeries that certainly can have at least --  
12 can have the risk of at least a significant  
13 or life-altering complications as what she is  
14 alleging in the Prolift.

15 MR. COMBS: And that said -- strike  
16 that.

17 Dr. Horbach, I don't have any  
18 further questions for you at this time.  
19 Thank you.

20 MR. SLATER: But I do. We're going  
21 to do this quick.

22 FURTHER EXAM BY COUNSEL FOR PLAINTIFFS

23 BY MR. SLATER:

24 Q Let's start where you just left off,  
25 Doctor.

1                   You have no idea what Pam Wicker would  
2   have chosen to do as between a Prolift or  
3   alternative procedures or treatments if she had  
4   been warned of additional risks? You have no way  
5   of knowing what she would have done; right?

6                   MR. COMBS: Object to form.

7                   THE WITNESS: No. I don't know --

8   BY MR. SLATER:

9           Q     It's a yes-or-no question.

10                  MR. COMBS: Objection.

11                  THE WITNESS: It's not a yes-or-no  
12                  question.

13   BY MR. SLATER:

14           Q     You can't answer it yes or no? That's  
15   fine.

16           A     Actually I will answer it no with being  
17   able to clarify.

18           Q     Doctor, tell me what about your training  
19   and your experience and your study of the  
20   literature and the medical records and everything  
21   else tells you that Pam Wicker would have chosen a  
22   Prolift no matter what she was told.

23                  Is that what you're telling us?

24           A     No.

25                  MR. COMBS: Object to form.

1 THE WITNESS: No.

2 BY MR. SLATER:

3 Q Okay. That's fine. You're not saying  
4 that, so I needed to know that. Okay.

5 The fact is: Whether or not Pam Wicker  
6 agreed to have a cosmetic procedure or some other  
7 procedure gives you no information as to what  
8 procedure Pam Wicker would have chosen if told  
9 about additional risks by Dr. Bercik; correct?

10 MR. COMBS: Object to form.

11 THE WITNESS: Your comment is  
12 additional risk. She was -- the risk that  
13 she or the complications that she  
14 experienced, she was warned about in the  
15 consenting for the procedure. So we're not  
16 talking about -- you're saying -- you're sort  
17 of implying that she had additional  
18 complications or risks that were not part of  
19 the consent process, and that's not the case.

20 BY MR. SLATER:

21 Q Okay. Move to strike.

22 Was Pam Wicker warned in the, by the --  
23 rephrase.

24 Did the IFU warn about the risk that one  
25 could have complex mesh erosions with the Prolift

1 that would require multiple operations? Was that  
2 warned about in the IFU?

3 MR. COMBS: Objection.

4 THE WITNESS: It does not state  
5 that specifically, but in her consent form --

6 BY MR. SLATER:

7 Q Doctor, that was my only question.  
8 Doctor, you're not going to get -- we're going to  
9 stick with my questions now. I don't want any  
10 more speeches with all due respect.

11 MR. COMBS: Object to colloquy by  
12 counsel.

13 BY MR. SLATER:

14 Q Next question: Was the word  
15 "dyspareunia" or painful sexual intercourse warned  
16 about in the IFU or patient brochure before Pam  
17 Wicker's surgery to get a Prolift?

18 MR. COMBS: Objection.

19 THE WITNESS: Those terms were not  
20 used.

21 BY MR. SLATER:

22 Q Do you know that Ethicon added pain with  
23 intercourse as a warning in a subsequent IFU after  
24 Pam Wicker's surgery? Did you know that was done?

25 A Yes.

1           Q     And you would agree with me that was a  
2     risk that should have been in the IFU from the  
3     very beginning; right?

4                     MR. COMBS:   Object to form.

5                     THE WITNESS:   No.

6     BY MR. SLATER:

7           Q     Do you disagree with Ethicon's decision  
8     to warn about pain with intercourse in a  
9     subsequent IFU after Pam Wicker's surgery?

10                    Is that a true statement?

11           A     No, I'm not saying that I disagree with  
12     it.  They're simply using a different term to  
13     explain pain issues.  They're adding an extra  
14     term.

15           Q     Move to strike.  I didn't ask for an  
16     explanation.

17                    Doctor, you made a statement that Pam  
18     Wicker's complications were warned about because  
19     these risks are essentially understood, and I  
20     wrote a note that you said basically all surgeons  
21     knew these things.  Okay?  I'm going to ask you a  
22     question about that.

23                    You have never studied the question of  
24     what surgeons across the United States understand  
25     or don't understand with regard to the risks of



1 the Prolift?

2 MR. COMBS: Object to form.

3 THE WITNESS: That statement is  
4 correct.

5 BY MR. SLATER:

6 Q Okay.

7 Now, you do not know the purpose of the  
8 IFU as intended by Ethicon; correct?

9 A What Ethicon's intent was in publishing  
10 the IFU, no.

11 Q -- have an understanding of, pursuant to  
12 FDA regulations, what the purpose of the IFU is;  
13 correct?

14 A I'm sorry. You cut out in the  
15 beginning.

16 Q You do not know what the purpose of the  
17 IFU is per FDA regulations; correct?

18 A I guess I would say that. Since the IFU  
19 was published prior, I mean the FDA did not end up  
20 approving or disapproving the IFU prior to it  
21 being published.

22 Q Do you know that the IFU that was relied  
23 on at the time of Pam Wicker's surgery, that  
24 before that time the FDA had required Ethicon to  
25 make material changes to the IFU that had not yet

1     been made by the time of Pam Wicker's surgery? Do  
2     you know that that occurred; yes or no?

3                     MR. COMBS: Object to form.

4                     THE WITNESS: I know that there was  
5             a requirement or request or statement by the  
6             FDA to change certain aspects of the IFU. I  
7             can't recall whether the timing was  
8             specifically before or after her surgery.

9     BY MR. SLATER:

10            Q     Do you know that the FDA made Ethicon  
11     change the wording in the patient brochure before  
12     Pam Wicker's surgery, but those changes were not  
13     made until after? Yes or no; do you know that  
14     that occurred?

15                     MR. COMBS: Object to form.

16                     THE WITNESS: That statement I  
17             would say no.

18     BY MR. SLATER:

19            Q     You made a statement just before --  
20     rephrase.

21                     You made a statement before about the  
22     fact that one should not advocate for a procedure  
23     when the only data available has short-term  
24     follow-up.

25                     Remember you made that statement a

1 little earlier?

2 A I'm not sure that I stated it  
3 specifically that way. What I stated was that in  
4 this particular situation, the procedure that Raz  
5 did with the netting did not have randomized  
6 trials and really didn't have any particular  
7 follow-up that he certainly had published. He may  
8 know that within his own practice, but there was  
9 no -- that information wasn't available in the  
10 literature.

11 Q You would agree with me that a medical  
12 device manufacturer should not advocate for a  
13 procedure involving one of their medical devices  
14 if they have no RCTs and all they have is  
15 short-term follow-up; correct?

16 MR. COMBS: Object to form.

17 THE WITNESS: No, I don't agree  
18 with that. I don't think that devices  
19 being --

20 BY MR. SLATER:

21 Q That's all I asked you, Doctor. I  
22 didn't ask you why. Don't care, honestly.

23 MR. COMBS: Again, I'll object to  
24 counsel being rude to the witness.

25 MR. SLATER: I'm not being rude.

1 I've been asking for four hours not to get a  
2 story beyond a simple answer. I'm trying to  
3 get the doctor out of here. She's told us  
4 she wants to leave. So I don't appreciate  
5 that I'm rushing and I'm getting long answers  
6 not asked for.

7 MR. COMBS: Again, I just  
8 appreciate the witness being treated with  
9 courtesy.

10 MR. SLATER: She's being treated  
11 with extreme courtesy, as are you.

12 BY MR. SLATER:

13 Q You said that in this ACOG bulletin,  
14 it's basically standing for the proposition in  
15 part and the part you're focused on,  
16 "musculoskeletal issues may be one of the  
17 etiologies for pelvic pain."

18 You said that a little earlier; correct?

19 A That musculoskeletal abnormalities is an  
20 etiology, not may be, but it is an etiology for  
21 pelvic pain.

22 I'm sorry. You cut out.

23 Q Sure.

24 Can you point me to any article, any  
25 clinical study that's been peer-reviewed and

1 accepted in the medical literature on the lists of  
2 medical literature that you supplied to me that  
3 stands for that proposition?

4 MR. COMBS: Object to form.

5 THE WITNESS: No.

6 Well, actually, I guess I should  
7 say yes, because the ACOG practice bulletin  
8 is a peer-reviewed document, so other, other  
9 things would -- studies I can't say, but  
10 ACOG's practice bulletin is a peer-reviewed  
11 document.

12 BY MR. SLATER:

13 Q Let's look at that ACOG bulletin for a  
14 minute. Page 81, please, where they talk about  
15 the heading "Musculoskeletal Disorders."

16 A Okay.

17 Q The thing they talk about is  
18 "musculoskeletal disorders as causes of or risk  
19 factors for chronic pelvic pain have not been  
20 widely discussed in gynecologic publications."

21 That's the first thing they say; right?

22 A Yes.

23 Q Let's go to the next paragraph. It  
24 talks about peripartum pelvic pain syndrome.

25 Do you see that?

1           A     Yes.

2           Q     And that relates to damage to pelvic  
3     ligaments, pelvic muscle weakness, and they talk  
4     about the weight of the fetus and "gravid uterus."

5                     Do you see that?

6           A     Yes.

7           Q     So that's a condition within the pelvis  
8     itself; correct?

9           A     Well, the fetus is -- yeah, I suppose a  
10    fetus is in the pelvis, although they're talking  
11    about lower spine and that type of thing, so  
12    that's a little bit outside the pelvis.

13          Q     Now let's look at -- well, let me just  
14    ask you this.

15                     There is no issue of lower back lumbar  
16    spine issues for Pam Wicker; correct?

17          A     She has not been diagnosed with anything  
18    in the lumbar spine as far as I can recall.

19          Q     Okay.

20                     Now, coming back to this, the third  
21    paragraph, you see it says "faulty posture"?

22          A     Yes.

23          Q     It actually says, "Faulty posture, in  
24    particular an exaggerated lumbar lordosis and  
25    thoracic kyphosis," that's K-Y-P-H-O-S-I-S,

1 "called typical pelvic pain posture."

2 Do you see that?

3 A Yes.

4 Q Pam Wicker does not have and has not had  
5 exaggerated lumbar lordosis; correct?

6 A She does not have an exaggerated lumbar.

7 Q Does not have thoracic kyphosis?

8 A No, that she does not.

9 Q And they say, "Other musculoskeletal  
10 disorders may cause or contribute to pelvic pain.  
11 These include trigger points, fibromyalgia, lumbar  
12 vertebral disorders, and pelvic floor myalgia."

13 Do you see that?

14 A Yes.

15 Q The only one of those that you offered  
16 the opinion that Pam Wicker has is pelvic floor  
17 myalgia, which in your opinion she has only had  
18 after the Prolift surgery; correct?

19 MR. COMBS: Object to form.

20 THE WITNESS: We only have evidence  
21 of symptoms after the Prolift surgery.

22 BY MR. SLATER:

23 Q There is nothing in this description of  
24 the musculoskeletal disorders that are being  
25 described in this bulletin that's talking about

1 osteoarthritis of the hip, one leg being longer  
2 than the other, a bone spur in the shoulder,  
3 rotator cuff surgery in the shoulder.

4 None of those conditions are described  
5 in this list of what the musculoskeletal disorders  
6 are; correct?

7 MR. COMBS: Object to form.

8 THE WITNESS: They are not listed  
9 specifically in that list.

10 BY MR. SLATER:

11 Q You said you're not an expert on the  
12 internal requirements of companies, companies like  
13 Ethicon who develop medical devices; correct?

14 A Correct.

15 Q And none of your opinions are based upon  
16 any of the internal workings or internal standards  
17 within Ethicon; correct?

18 MR. COMBS: Object to form.

19 THE WITNESS: Correct.

20 BY MR. SLATER:

21 Q Your opinions are based solely on your  
22 own personal opinions based on your experience;  
23 correct?

24 MR. COMBS: Object to form.

25 THE WITNESS: No.



1 BY MR. SLATER:

2 Q Your opinions are based on no -- well,  
3 rephrase.

4 You are not basing your opinions at all  
5 on any of the internal standards applied by  
6 Ethicon or any understanding of why Ethicon made  
7 any decision; correct?

8 A Yes.

9 Q You were asked about whether or not you  
10 are aware of any articles describing a clinical  
11 correlation to clinical outcomes in patients with  
12 respect to porosity, and you said you're not  
13 familiar with any; correct?

14 A I, I stated that, yes.

15 Q So number one, if any such articles  
16 exist, you just don't know about them; right?

17 A I think that -- I can't answer that as a  
18 yes or no, because I would have to make an  
19 additional qualification of the statement that you  
20 made, because you're not quite phrasing the way --  
21 you're not -- you made a statement that is not  
22 accurately representing what I said.

23 Q Well, I'm asking you right now.

24 Are you familiar with any study  
25 evaluating the clinical correlation with regard to

1 outcomes for patients with respect to the porosity  
2 of pelvic mesh?

3 A I'm familiar, obviously, with the  
4 studies we've talked about that look at the  
5 porosity of the mesh in patients with a mesh  
6 problem and a problem -- and a potential  
7 complication from the surgery. I am not aware of  
8 any papers or articles that compare that type of  
9 porosity and tissue sample, et cetera, in a  
10 patient who is a normal post-operative patient  
11 without clinical symptoms.

12 Q You certainly would agree with me that  
13 Klinge and Klosterhoff have written multiple  
14 articles where they have opined, based on their  
15 evaluation of explanted meshes and their study of  
16 the explants, that porosity has a direct  
17 contributing factor -- is a direct contributing  
18 factor to poor clinical outcomes when the porosity  
19 is not adequate.

20 You're familiar with that; right?

21 MR. COMBS: Object to form.

22 THE WITNESS: I'm familiar with  
23 that opinion.

24 BY MR. SLATER:

25 Q You have no idea what Ethicon thinks

1 with regard to whether or not porosity can be a  
2 contributing factor to poor clinical outcomes for  
3 patients with the Prolift or other pelvic mesh  
4 devices; correct?

5 A I don't think that that's a correct  
6 statement. I have -- I'm aware of some documents  
7 within Ethicon discussing the pros and cons of  
8 different meshes and the preference to use or  
9 preference not to use, you know, a small pore mesh  
10 versus a larger pore mesh. I'm aware of those  
11 types of documents from Ethicon and their  
12 discussions.

13 Q So you certainly are aware -- rephrase.

14 You're certainly aware that Ethicon  
15 believes that you need to have large pores that  
16 will maintain a one-millimeter size in actual use  
17 in order to try to minimize the risk of scar  
18 tissue-related complications.

19 Are you aware of that?

20 MR. COMBS: Object to form.

21 THE WITNESS: That statement was  
22 fine for the beginning part but not  
23 necessarily for the end part. I think that  
24 Ethicon was aware that, that they felt there  
25 was a benefit for having a, a mesh that

1 maintained -- that was a larger pore mesh.  
2 The statement of, you made of saying that  
3 maintain that in the patient, et cetera, et  
4 cetera, et cetera, after that, I am not aware  
5 of that part of the documentation that -- of  
6 Ethicon.

7 BY MR. SLATER:

8 Q Do you feel that your expertise covers  
9 the question of whether or not a mesh to be used  
10 for the use like the Prolift needs to maintain a  
11 one-millimeter pore size under strain and actual  
12 use within the body when forces are actually  
13 applied? Do you feel like you have the expertise  
14 to answer that question to a reasonable degree of  
15 medical probability?

16 MR. COMBS: Object to form.

17 THE WITNESS: I guess I have to say  
18 I don't know that I can answer that question.

19 MR. SLATER: I have no other  
20 questions.

21 FURTHER EXAM BY COUNSEL FOR DEFENDANTS

22 BY MR. COMBS:

23 Q Dr. Horbach, just a housekeeping matter.  
24 I don't know if we did or didn't, if the consent  
25 was marked, so I'm going to mark it.

1 (Exhibit 22 was marked for  
2 identification.)

3 BY MR. COMBS:

4 Q Let me hand you what's been marked as  
5 Exhibit 22.

6 What is that document?

7 A This is the consent form that  
8 Mrs. Wicker signed on September 8, 2008 regarding  
9 the surgery that she underwent in October.

10 Q Dr. Horbach, was the date of the ACOG  
11 publication that we marked as Exhibit 21 2004?

12 A I'm sorry. Yes, it was marked 2004.

13 Q Now, are your findings regarding  
14 Mrs. Wicker's faulty posture set forth in the IME  
15 section of the report?

16 A Yes.

17 Q Have you treated numerous patients that  
18 have exhibited musculoskeletal problems during  
19 your clinical practice?

20 A Hundreds.

21 MR. SLATER: Objection.

22 BY MR. COMBS:

23 Q And is your treatment and clinical  
24 practice regarding those patients part of your  
25 foundation for your opinion in this case on that

1 issue?

2 MR. SLATER: Objection.

3 THE WITNESS: Yes.

4 MR. COMBS: I don't have any  
5 further questions.

6 FURTHER EXAM BY COUNSEL FOR PLAINTIFFS  
7 BY MR. SLATER:

8 Q One question to follow up that.

9 For any patients who you say had  
10 musculoskeletal issues, are you able to give me  
11 the entire profile of all of the conditions they  
12 had and their full relevant medical history on  
13 each one of those right now?

14 A Could I name my patients and each  
15 individual problem that they had? No, but I could  
16 certainly tell you the types of problems that  
17 these patients experience that we see that are  
18 associated with these kind of conditions.

19 Q I'm asking you with these so-called  
20 patients, if you were to say, well, these are my  
21 patients with musculoskeletal conditions that I  
22 think led to whatever condition you say it led to,  
23 would you be able to say, well, let me tell you  
24 the rest of the profile, other surgeries they had,  
25 other comorbidities, their entire profile? Would

1     you be able to give that to me right now for every  
2     one of those patients?

3             A     Not for every one, but I certainly could  
4     for some.

5                     MR. SLATER: I have no other  
6     questions.

7                     MR. COMBS: No questions.

8                     THE VIDEOGRAPHER: Our time now is  
9     6:15 p.m. This concludes our videotaped  
10    deposition.

11                    THE REPORTER: Are you ordering a  
12    transcript?

13                    MR. SLATER: Yes.

14                    MR. COMBS: Yes.

15                    (Signature having not been  
16    waived, the video deposition of  
17    NICOLETTE HORBACH, M.D. was  
18    concluded at 6:15 p.m.)

19

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1 CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

2  
3  
4  
5  
6  
7 I, Laurie Bangart, Registered  
Professional Reporter, Certified Realtime  
8 Reporter, the officer before whom the  
foregoing deposition was taken, do hereby  
9 certify that the foregoing transcript is a  
true and correct record of the testimony  
10 given; that said testimony was taken by me  
stenographically and thereafter reduced to  
11 typewriting under my supervision; and that I  
am neither counsel for, related to, nor  
12 employed by any of the parties to this case  
and have no interest, financial or otherwise,  
13 in its outcome.

14 IN WITNESS WHEREOF, I have hereunto  
set my hand and affixed my notarial seal this  
15 3rd day of December, 2013.

16 My commission expires: March 14th, 2016  
17  
18  
19

20 \_\_\_\_\_  
LAURIE BANGART  
NOTARY PUBLIC IN AND FOR  
21 THE DISTRICT OF COLUMBIA  
22  
23  
24  
25



INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.



ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
hereby certify that I have read the  
foregoing pages, and that the same  
is a correct transcription of the answers  
given by me to the questions therein  
propounded, except for the corrections or  
changes in form or substance, if any,  
noted in the attached Errata Sheet.

\_\_\_\_\_  
NICOLETTE S. HORBACH, M.D. DATE

Subscribed and sworn  
to before me this  
\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
Notary Public